

EXHIBIT 1

RULE 26 EXPERT REPORT OF DR. NIALL GALLOWAY

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. The opinions, which are held and expressed are as follows:

I. QUALIFICATIONS

I am an Associate Professor of Surgery (Urology) at the Emory University School of Medicine in Atlanta, Georgia. I obtained a M.B., Ch.B. from the University of Aberdeen Medical School in 1974 and went on to Edinburgh, Scotland for internship. I was awarded Fellowship of the Royal College of Surgeons of England in 1979 and was later awarded Fellowship of the Royal College of Surgeons of Edinburgh. I completed my residency in surgery in 1980 at Royal United Hospital in Bath, England.

I was appointed Lecturer in Surgery/Urology at the University of Edinburgh in 1982. At that time, I was able to initiate collaboration between the Urology and Gynecology specialties, which led to the creation of the first multidiscipline Continence Clinic in Scotland. I was appointed Senior Registrar in 1984 at the University Hospital of Wales in Cardiff. In 1986, I was invited to Duke University as a Research Fellow and was later appointed to the faculty as visiting professor. I was invited to join the faculty of Emory University School of Medicine in Atlanta in 1988. In 1992, I co-founded the Emory Continence Center, where I presently serve as Medical Director. The Continence Center is staffed by Urology, Gynecology and Gastroenterology physicians, as well as specialty trained continence nurses. The center provides all aspects of comprehensive assessment and treatments for pelvic floor dysfunction including incontinence, prolapse, bowel problems, and pelvic pain.

I was elected to the Atlanta Urological Association in 1990, the Southeastern Section of the American Urological Association AUA in 1993, and by invitation to the National Urological Forum in 1994. From 2007 to 2008, I served on the Medical Executive Committee of the Georgia Urological Association. I have recently stepped down from the position of Chairman of the Board of Directors for the National Association for Continence, after serving two consecutive terms. I have been a member of the editorial board for the European Association of Urology since 2011. I am an author of many book chapters, abstracts, and peer reviewed journal articles and have given presentations regarding pelvic floor disorders, including pelvic organ prolapse (POP) and stress urinary incontinence (SUI). I have recently published a new book titled "Seeking Symmetry: Finding Patterns in Human Health".

My experience, education, and training are more fully summarized in my curriculum vitae, attached to this report as Exhibit A.

II. INTRODUCTION

Over the past several years, more and more of my surgical practice consists of handling complications resulting from the placement of synthetic mesh in the vagina for POP and SUI. I see several new patients every month with mesh-related complications. Synthetic mesh can take a trivial condition and raise a host of aggravating problems that interfere with activities of normal life. Surgeons and physicians saw these problems soon after these products were introduced. The most common complaints are pain and dyspareunia from banding, scarring, shrinkage, and

contraction of the mesh.

In the introduction of trans-vaginally-placed mesh devices into the medical marketplace for the treatment of SUI, a basic principle of medicine was violated; that is, “Do No Harm.” These products were introduced into the marketplace despite red flag alerts from the hernia experience and literature, the known uniqueness of the vaginal environment, and early adverse event reports. As a result, a public health crisis has been created. Women have been forced to deal with serious and unanticipated complications and doctors have been confronted with conditions that are difficult, and sometimes impossible, to treat. All of this was predictable.

The opinions expressed in this report are based on my experience treating women with mesh complications and surgically removing mesh and the medical and scientific literature. All my opinions have been made to a reasonable degree of medical certainty.

III. DISCUSSION

The extrapolation of the placement of mesh in other parts of the body (e.g., the abdominal wall) to the vagina was an erroneous idea. The vagina is a unique environment. Although the vagina can be forgiving (as in accommodating a vaginal birth and the remarkable healing afterwards), it can also be as hostile as any area in the human body. The vagina is also extremely variable from one individual to the next and over time. Synthetic mesh devices failed to take into consideration biological and anatomical differences of the vagina.

1. A permanent synthetic mesh device designed to be placed in a contaminated environment (i.e., vagina) contradicts basic surgical principles.

The vagina is populated and colonized with numerous bacteria and yeast and is located immediately adjacent to the bowel and anus.

The vagina is the only area of the body in which polypropylene mesh is placed in a bacteria laden surgical field. In fact, the placement of polypropylene mesh is actually contraindicated in this setting. Choi reported on the outcomes of 33,832 cases of ventral hernia repair with mesh. The authors of this study concluded, “there is a significant increase in risk of postoperative occurrences following VHRs [ventral hernia repairs] using mesh in clean-contaminated and contaminated cases relative to clean cases.” The study recommended avoiding the use of mesh in any level of contamination.¹

Culligan and others have shown that bacterial colonization exists even after attempts to sterilize the vagina in preparation for surgery. Even following standard surgical scrub with providone-iodine and pre-operative antibiotics, the majority of women (52%) had positive cultures at 30 minutes. Bacteria found in baseline (preoperative) vaginal cultures included anaerobic pathogens (45%), staphylococcus aureus (16%), alpha-hemolytic streptococcus (23%), E. coli (42%),

¹ Choi, J. J., Palaniappa, N. C., Dallas, K. B., Rudich, T. B., Colon, M. J., & Divino, C. M. (2012). Use of mesh during ventral hernia repair in clean-contaminated and contaminated cases: outcomes of 33,832 cases. *Ann Surg*, 255(1), 176-180. doi: 10.1097/SLA.0b013e31822518e6

klebsiella pneumonia (13%), and Group B streptococci (13%).²

Synthetic mesh materials are prone to infections and “notoriously resistant to antibiotics and host defenses, and to persist until the biomaterial is removed.”³ In a prospective study of 64 consecutive patients undergoing vaginal implantation of a lightweight, collagen-coated monofilament polypropylene mesh, Vollebregt, et al. showed that 96 % of the mesh arms were colonized by different types of bacteria.⁴ The bacteriological analysis of 16 meshes removed because of complications following the surgical management of urinary incontinence or POP showed multimicrobial infection in 31% of cases, including *P. mirabilis* (in 25%), *E. coli*, *Staphylococcus*, *Streptococcus* and *Enterococcus* [8]. Bacterial contamination was found in all meshes, even in a case of repeat surgery for mesh shrinkage with no erosion. Bacterial density was low (<103 CFU/mL) in 43% of cases but in others reached 10 CFU/mL.⁵ Lactobacilli dominate the normal bacteria seen in the vagina and routinely produce hydrogen peroxide and lactic acid. “Their toxic and inhibitory effect against the overgrowth of pathogens in the vagina is documented by in vitro studies.”⁶ This issue becomes important since peroxides are implicated in the oxidation and degradation of polypropylene in the human body.

Infection, even subclinical, has been linked with misbehaving mesh and mesh complications, including chronic infection and abscess, wound separation, erosion, fistulae, shrinkage, chronic inflammation, degradation, and functional bladder problems. In a study by Wang, bacterial colonization was also linked to de novo urge symptoms after placement of mesh. In that study, 83% of patients with urge symptoms had bacteria identified in the excised tissue, compared to 5% in controls.⁷

The difference in the abdomen and vagina was demonstrated as early as 2000. Visco et al., reporting on their experience with sacral colpopexy, noted that “the rate of mesh erosion is higher and the time to mesh erosion is shorter with combined vaginal- abdominal sacral colpoperineopexy with vaginal suture and vaginal mesh placement in comparison with abdominal sacral colpopexy.” The erosion rate with traditional sacral colpopexy was noted to be 4.5% whereas the erosion rate when mesh was placed vaginally was 40%. As a result, the investigators discontinued the practice of attaching vaginal mesh directly to the perineal body and concluded that “mesh erosions may be

² Culligan, P., Heit, M., Blackwell, L., Murphy, M., Graham, C. A., & Snyder, J. (2003). Bacterial colony counts during vaginal surgery. *Infect Dis Obstet Gynecol*, 11(3), 161-165. doi: 10.1080/10647440300025515

³ de Tayrac, R., & Letouzey, V. (2011). Basic science and clinical aspects of mesh infection in pelvic floor reconstructive surgery. *Int Urogynecol J*, 22(7), 775-780. doi: 10.1007/s00192-011-1405-4

⁴ Vollebregt, A., Troelstra, A., & van der Vaart, C. H. (2009). Bacterial colonisation of collagen-coated polypropylene vaginal mesh: are additional intraoperative sterility procedures useful? *Int Urogynecol J Pelvic Floor Dysfunct*, 20(11), 1345-1351. doi: 10.1007/s00192-009-0951-5

⁵ Boulanger, L., Boukerrou, M., Rubod, C., Collinet, P., Fruchard, A., Courcol, R. J., & Cosson, M. (2008). Bacteriological analysis of meshes removed for complications after surgical management of urinary incontinence or pelvic organ prolapse. *Int Urogynecol J Pelvic Floor Dysfunct*, 19(6), 827-831. doi: 10.1007/s00192-007-0537

⁶ Mijac, V. D., Dukic, S. V., Opavski, N. Z., Dukic, M. K., & Ranin, L. T. (2006). Hydrogen peroxide producing lactobacilli in women with vaginal infections. *Eur J Obstet Gynecol Reprod Biol*, 129(1), 69-76. doi: 10.1016/j.ejogrb.2005.11.036

⁷ Wang, A. C., Lee, L. Y., Lin, C. T., & Chen, J. R. (2004). A histologic and immunohistochemical analysis of defective vaginal healing after continence taping procedures: a prospective case-controlled pilot study. *Am J Obstet Gynecol*, 191(6), 1868-1874. doi: 10.1016/j.ajog.2004.09.017

the only clinical manifestations of a bacterial contamination.”⁸

It was foreseeable that placing mesh in a contaminated environment would create problems, e.g. de novo infection, abscess, erosion, and pain.

In my opinion, inserting polypropylene mesh (known to be problematic when placed in a contaminated field) in the vagina (known to contain bacteria, known to be close to the anus, and known to be incapable of sterilization) represents a serious flaw in the design of Ethicon’s mesh devices.

2. Polypropylene becomes rigid when placed in the vagina - an organ that needs to remain flexible and compliant to function. This phenomenon leads to complications not seen with traditional pelvic surgery.

The pelvic floor is a dynamic trampoline of resilient muscles and connective tissue structures. It needs to be supple, flexible, and springy. The muscles and loose connective tissue are critical for normal pelvic support. They must contract to maintain pelvic support for continence. They must relax to permit voluntary urination and to initiate the act of defecation. In the female, the pelvic floor must relax and lengthen enormously to allow the passage of a full-term fetus during childbirth, yet it must contract again after delivery to permit all of the normal functions to be maintained. It must accommodate movement and forces associated with activities of daily living, such as coughing, walking, exercise, bladder filling, defecation, and sexual relations. Scar plate and mesh stiffness are incompatible with the natural functioning of the vagina.

Mesh embrittlement, resulting in restriction of movement of the abdominal wall, has been recognized in hernia repairs for some time. In 2001, Junge and Klinge used fresh cadavers to test the elasticity of abdominal wall mesh. The authors reported that the implantation of mesh “leads to considerable restriction of abdominal wall mobility in up to 25% of cases. Rigidity and discomfort, especially at the edge of the mesh, are frequent reported complaints.” Junge stated that tensile strength and flexibility must be taken into account in the “complex interactions of the anatomic structures” where the mesh is placed. Inadequate pore size and geometry result in increased shrinkage and scar reaction. Junge found most of the meshes he tested to be “inappropriately stiff” and these turned into a “hard sheet in the post-implantation period.”⁹

“The mechanism of action of a permanent prosthetic mesh is to incite an intense fibroplastic foreign body response, resulting in the development of a strong scar plate interface. Although this may provide a strong and durable repair, the chronic inflammatory response to the mesh may also lead to chronic pain in some patients, a sensation of being able to feel the mesh, and stiffness of the abdominal wall with loss of compliance.”¹⁰ In addition to stiffness from scarring and fibrosis,

⁸ Visco, A. G., Weidner, A. C., Barber, M. D., Myers, E. R., Cundiff, G. W., Bump, R. C., & Addison, W. A. (2001). Vaginal mesh erosion after abdominal sacral colpopexy. *Am J Obstet Gynecol*, 184(3), 297-302. doi: 10.1067/mob.2001.109654

⁹ Junge, K., Rosch, R., Klinge, U., Schwab, R., Peiper, C., Binnebosel, M., . . . Schumpelick, V. (2006). Risk factors related to recurrence in inguinal hernia repair: a retrospective analysis. *Hernia*, 10(4), 309-315. doi: 10.1007/s10029-006-0096-0

¹⁰ Bellows, C. F., Shadduck, P. P., Helton, W. S., & Fitzgibbons, R. J. (2011). The design of an industry- sponsored randomized controlled trial to compare synthetic mesh versus biologic mesh for inguinal hernia repair. *Hernia*, 15:325-332. doi: 10.1007/s10029-010-0773-x

degradation of the polymer itself results in stiffening.¹¹

The loss of vaginal compliance and function from hardened mesh is something I commonly see in my practice. Mesh, when surgically removed, does not look or feel anything like it does in the package.

In my opinion, placing polypropylene mesh (known to become rigid and restrictive of motion) in the vagina (known to require flexibility and compliance for proper function) represents a serious flaw in the design of Ethicon's vaginal mesh devices.

3. Degradation, chronic inflammation, and possible toxicity create unknown long-term effects in a woman's vagina.

A chronic inflammatory and foreign body reaction to transvaginally placed mesh occurs in all patients.¹² Additionally, Polypropylene was known to degrade in the human body as early as 1986.¹³ This was reported again by Coda and Bendavid in 2003¹⁴ and frequently since that time. Degradation and mesh surface changes contribute to the inflammatory response and scar plate formation by harboring bacteria, releasing toxins, and creating a jagged surface. In a 2007 study of explanted polypropylene hernia mesh, Costello et al. reported cracks, surface roughness, and peeling – all indicative of degradation. The authors also recognized reduced compliance. “These findings correspond to increased abdominal wall stiffness and patient complaints of pain and restricted mobility. During the implantation period, the surface of the explanted materials stimulated the foreign body response that, in turn, produced oxidants such as hydrogen peroxide and hypochlorous acid.”¹⁵

Clave confirmed degradation in transvaginal mesh explants in 2010. Clave questioned “the prevailing understanding of PP as inert” based on his examination of 100 explants. In Clave's work, “not all types of PP implants degraded equally. The PP implants degraded more in the presence of an acute infection or chronic inflammation.” Clave considered several hypotheses for

¹¹ Costello CR, Bachman SL, Ramshaw BJ, Grant SA. Materials characterization of explanted polypropylene hernia meshes. *Journal of biomedical materials research Part B, Applied biomaterials*. 2007;83(1):44-9; C.R. Costello SLB, S.A. Grant, D.S. Cleveland, T.S. Loy and B.J. Ramshaw. Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants From a Single Patient. *Surgical Innovation*. 2007;14(3):168-76.; Fayolle B, Audouin L, Verdu J. Oxidation induced embrittlement in polypropylene - a tensile testing study. *Polymer Degradation and Stability*. 2000;70(2000):333-40; Fayolle B, Audouin L, Verdu J. Initial steps and embrittlement in the thermal oxidation of stabilised polypropylene films. *Polymer Degradation and Stability*. 2002;75:123-9; Fayolle B, Audouin L, George GA, Verdu J. Macroscopic heterogeneity in stabilized polypropylene thermal oxidation. *Polymer Degradation and Stability*. 2002;77:515-22; Liebert TC, Chartoff RP, Cosgrove SL, McCuskey RS. Subcutaneous implants of polypropylene filaments. *Journal of biomedical materials research*. 1976;10(6):939-51; Anderson JM, Rodriguez A, Chang DT. Foreign body reaction to biomaterials. *Seminars in immunology*. 2008;20(2):86-100.

¹² Iakovlev V., C. E., Steege J (2014). "Pathology of Explanted Transvaginal Meshes." *International Journal of Medical, Health, Pharmaceutical and Biomedical Engineering* 8(9).

¹³ Jongebloed, W. L., & Worst, J. F. Degradation of polypropylene in the human eye: a SEM-study. *Documenta Ophthalmologica. Advances In Ophthalmology*, 1986: 64(1), 143-152.

¹⁴ Coda, A., Bendavid, R., Botto-Micca, F., Bossotti, M., & Bona, A (2003). Structural alterations of prosthetic meshes in humans. *Hernia: The Journal Of Hernias And Abdominal Wall Surgery*, 7(1), 29-34

¹⁵ Costello, C. R., Bachman, S. L., Grant, S. A., Cleveland, D. S., Loy, T. S., & Ramshaw, B. J. (2007). Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient. *Surg Innov*, 14(3), 168-176. doi: 10.1177/1553350607306356

this degradation, including large detachments and hematomas causing the massive accumulation of blood-derived fatty acids, the diffusion of organic molecules into the polymer, and radical oxidation due to the septic environment that accompanies acute infections and chronic inflammation.¹⁶ Several recent studies have confirmed degradation in explanted vaginal mesh.¹⁷

In my opinion, placing a material that degrades, releases potentially toxic chemicals, and creates a chronic inflammatory response, is a flaw in the design of Ethicon's vaginal mesh devices.

4. Ethicon's transvaginal mesh devices demonstrate a variable and unpredictable rate of shrinkage and retraction, rendering performance that is unreliable at best.

In 1998, Klinge and Klosterhalfen reported a 30-50% shrinkage rate with polypropylene mesh.¹⁸ In practice, surgeons knew for even longer that a mesh piece must be cut significantly larger than the defect to avoid failure at the edges, indicating concern for shrinkage and puckering. Tunn confirmed shrinkage using ultrasound evaluation of transvaginal mesh in 2007.¹⁹ Jacquetin and Cosson linked mesh retraction with vaginal tenderness, painful intercourse, pain, sometimes permanent, and possibly urinary dysfunction.²⁰

Because of shrinkage and retraction, there is no way to place synthetic mesh in a "tension-free" manner and it is impossible to know how much tension will eventually result. The degree of shrinkage is unpredictable and varies from one individual to the next – some women are high responders and others are low responders to biomaterials, including polypropylene. The amount of shrinkage has also been shown to vary based on the location in which it is placed (between the peritoneum and muscle or above the fascia).²¹ Shrinkage is magnified with infection, even subclinical contamination, which has been found to occur in almost all transvaginally placed meshes.²² Letouzey showed polypropylene mesh contraction to be progressive, demonstrating a linear evolution with time. Ultrasound reconstruction "showed a mean contraction of 30%, 65%,

¹⁶ Clave, A., Yahi, H., Hammou, J. C., Montanari, S., Gounon, P., & Clave, H. (2010). Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. *Int Urogynecol J*, 21(3), 261-270. doi: 10.1007/s00192-009-1021-8

¹⁷ Iakovlev V. MG, Blaivas J. Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh is Not Inert [Abstract]. International Continence Society Meeting Annual Meeting. 2014; Iakovlev V., C. E., Steege J (2014). "Pathology of Explanted Transvaginal Meshes." *International Journal of Medical, Health, Pharmaceutical and Biomedical Engineering* 8(9); Iakovlev, V., Guelcher, S., Bendavid, R. (2014). "In vivo degradation of surgical polypropylene meshes: A finding overlooked for decades." *Virchows Arch Suppl 1: S35*; Tzartzeva K, L. D., Baniyadi M, Minary-Jolandan M, Zimmermann P (2014). "In-Depth Nan-Investigation of Vaginal Mesh and Tape Fiber Explants in Women [Abstract]." *ICS* 366.

¹⁸ Klinge, U., Klosterhalfen, B., Muller, M., Ottinger, A. P., & Schumpelick, V. (1998). Shrinking of polypropylene mesh in vivo: an experimental study in dogs. *Eur J Surg*, 164(12), 965-969. doi: 10.1080/110241598750005156

¹⁹ Tunn, R., Picot, A., Marschke, J., & Gauruder-Burmester, A. (2007). Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele. *Ultrasound Obstet Gynecol*, 29(4), 449-452. doi:10.1002/uog.3962

²⁰ Jacquetin, B., & Cosson, M. (2009). Complications of vaginal mesh: our experience. *Int Urogynecol J Pel Floor Dysfunct*, 20(8), 893-896. doi:10.1007/s00192-009-0926-6

²¹ Garcia-Urena, M. A., Vega Ruiz, V., Diaz Godoy, A., Baez Perea, J. M., Marin Gomez, L. M., Carnero Hernandez, F. J., & Velasco Garcia, M. A. (2007). Differences in polypropylene shrinkage depending on mesh position in an experimental study. *Am J Surg*, 193(4), 538-542. doi: 10.1016/j.amjsurg.2006.06.045.

²² Mamy, L., Letouzey, V., Lavigne, J. P., Garric, X., Gondry, J., Mares, P., & de Tayrac, R. (2011). Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. *Int Urogynecol J*, 22(1), 47-52. doi: 10.1007/s00192-010-1245-7

85% at a mean follow up of 3 years (n 5 12), 6 years (n 5 16), 8 years (n 5 12) respectively.”²³

Chronic pelvic pain is the most common clinical symptom associated with mesh shrinkage. “The concurrent processes of tissue in growth and mesh shrinkage may cause significant pain, particularly in patients who undergo trocar-guided mesh placement. Adherence of the mesh arms in the lateral pelvic wall is a point against which tension increases during the processes of tissue in growth and mesh shrinkage.” Other complications related to shrinkage and not warned about by Bard include sexual impairment, loss of vaginal function due to narrowing/shortening, functional bladder and bowel symptoms, and need for multiple, difficult corrective procedures.²⁴ Chronic pain from mesh distortion and shrinkage is something I commonly see in my practice.

In a study by Margulies, “[t]he repercussions of mesh shrinkage in the vagina vs the abdominal wall can be severe and functionally devastating. Normal urinary, sexual, and defecatory functions require a vagina that is compliant and whose walls can easily and painlessly change conformation. With excessive stiffness of the vaginal walls secondary to mesh that has undergone shrinkage, it is possible that dyspareunia, defecatory, and urinary dysfunction could result.” The conditions described in this article are something I commonly see in my practice.²⁵

An example of a clinical study exhibiting the defects in armed transvaginal mesh was published by Feiner and Maher in 2010, based on a series of patients seen in 2007- 2008. This paper described the “substantial morbidity” associated with “vaginal mesh contraction”. “Clinical presentation included severe vaginal pain aggravated by movement (17 of 17), dyspareunia in all sexually active women (14 of 14), and focal tenderness over contracted portions of the mesh on vaginal examination (17 of 17), commonly involving the lateral fixation arms. Mesh erosion (9 of 17), vaginal tightness (7 of 17), and shortening (5 of 17) were frequently present.” This paper set out to describe the clinical implications of the in vivo shrinkage of polypropylene mesh up to 50% if its original size that had been previously described both in animal studies and women.²⁶ Vaginal

²³ Letouzey, V., Huberlant, S., Lavigne, J., Mares, P., Garric, X. & De Tayrac, R. (2012). Is polypropylene mesh coated with antibiotics is efficient to prevent mesh infection and contraction in an animal infectious model? [Abstract]. 37th Annual Meeting of the International Urogynecological Association, 193.

²⁴ Rogo-Gupta, L., & Raz, S. (2013). Pain Complications of Mesh Surgery. In H. B. Goldman (Ed.), *Complications of Female Incontinence and Pelvic Reconstructive Surgery* (pp. 87-105): Humana Press.

²⁵ Margulies, R. U., Lewicky-Gaupp, C., Fenner, D. E., McGuire, E. J., Clemens, J. Q., & Delancey, J. O. (2008). Complications requiring reoperation following vaginal mesh kit procedures for prolapse. *Am J Obstet Gynecol*, 199(6), 678 e671-674. doi: 10.1016/j.ajog.2008.07.049

²⁶ Feiner, B., & Maher, C. (2010). Vaginal mesh contraction: definition, clinical presentation, and management. *Obstet Gynecol*, 115(2 Pt 1), 325-330. doi: 10.1097/AOG.0b013e3181cbca4d

contraction from mesh procedures is something I commonly see in my practice.

In my opinion, using a material that shrinks and retracts significantly, but in a variable and asymmetric fashion, is a flaw in design.

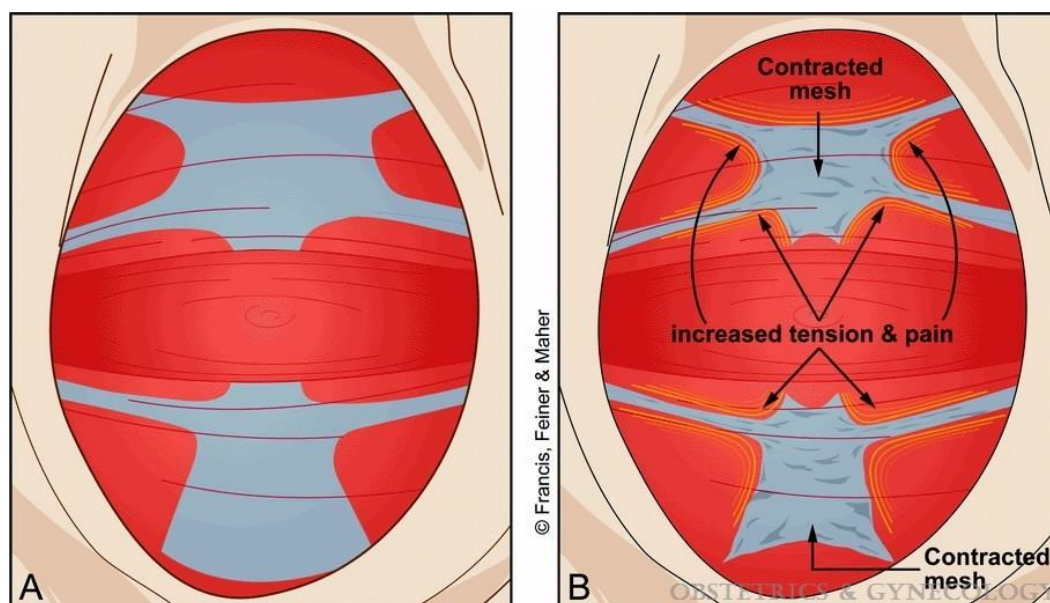
5. Ethicon's transvaginal mesh devices damage and entrap nerves, sometimes resulting in chronic and permanent pain syndromes that are refractory to treatment.

Unlike routine postoperative pain that is typically self-limiting, mesh-related pain is often atypical in character, onset, duration, and location. Neuropathic pain associated with mesh is something I see commonly in my practice and can be very difficult to treat.

Nerve injuries occur commonly with transvaginally placed mesh. The trocars, blindly placed, traverse through tissue densely innervated with large nerves and smaller nerve branches. Nerves can be traumatized during the procedure itself. Postoperative nerve injuries have been reported to occur at a rate of 9.4% with transobturator slings.²⁷

Nerve damage can also result from nerve inflammation and nerve entrapment resulting from the chronic inflammatory response and fibrosis surrounding the mesh. The nerves most commonly involved with a transobturator sling are the intermediate femoral cutaneous, posterior cutaneous, pudendal, perineal, inferior anal, and the obturator nerves. The ilioinguinal and iliohypogastric nerves are more commonly involved with the retropubic approach.

In a 2005 Klosterhalfen post-retrieval study of hernia mesh, most explants from all the patients with chronic pain in their medical history indicate nerve fibers and fascicles in the interface of the mesh. Klosterhalfen further stated that "clinical trials report high percentages of patients with



Feiner, Benjamin; Maher, Christopher: *Obstetrics & Gynecology*. 115(2, Part 1): 325-330, February 2010.

²⁷ Richter, H. E., Albo, M. E., Zyczynski, H. M., Kenton, K., Norton, P. A., Sirls, L.T., Litman, H. J. (2010). Retropubic versus transobturator midurethral slings for stress incontinence. *N Engl J Med*, 362(22), 2066-2076. doi: 10.1056/NEJMoa0912658

chronic pain after hernia repair, including mesh repair. In contrast to neuropathy-related complaints after intraoperative damage of nerve fibers with pain immediately after surgery, the onset of chronic pain as a consequence of the FBR [foreign body reaction] is typically more than 1 year after hernia repair. In the postretrieval study, most explants from all the patients with chronic pain in their medical history, indicate nerve fibers and fascicles in the interface of the mesh.”²⁸

Drs. Iakovlev and Ben-David recently published an article in the peer-reviewed literature titled, “Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain”. This paper describes nerve ingrowth with hernia mesh and reports a new mesh-related pain disorder characterized by its slow onset, its progressive and unrelenting nature, and its unresponsiveness to treatment including mesh removal.²⁹ Drs. Iakovlev and Blaivas have also published their findings of nerve damage in vaginal mesh – occurring with a much greater density than the abdominal wall. These published reports of explanted mesh pathology also describe chronic inflammation, scarring and fibrosis, deformation, and degradation.³⁰

Histological findings in transvaginal mesh:

Rogo-Gupta stressed the importance of a thorough understanding of pelvic anatomy in evaluating complex mesh pain.³¹ Mesh can become incorporated into muscles, resulting in fibrosis, restriction and pain with movement. Muscular injury with armed mesh may cause severe pain with walking or joint movement. Patients who undergo posterior compartment mesh repair with trocar-guided lateral mesh arms may experience pain in the levator muscles or gluteus maximus. Gluteus maximus innervation is provided by the inferior gluteal nerve (S1). Patients may present with pain exacerbated by sitting, external hip rotation, and hip extension. Injury to the external anal sphincter

²⁸ Klosterhalfen, B., Junge, K., & Klinge, U. (2005). The lightweight and large porous mesh concept for hernia repair. *Expert Rev Med Devices*, 2(1), 103-117. doi:10.1586/17434440.2.1.103

²⁹ Bendavid, R., Lou, W., Koch, A., Iakovlev, V. (2014). "Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain." *International Journal of Clinical Medicine* 5: 799-810.

³⁰ Iakovlev V., M. G., Blaivas J. (2014). "Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh is Not Inert [Abstract]." *International Continence Society Meeting Annual Meeting*.

³¹ Rogo-Gupta (2013).

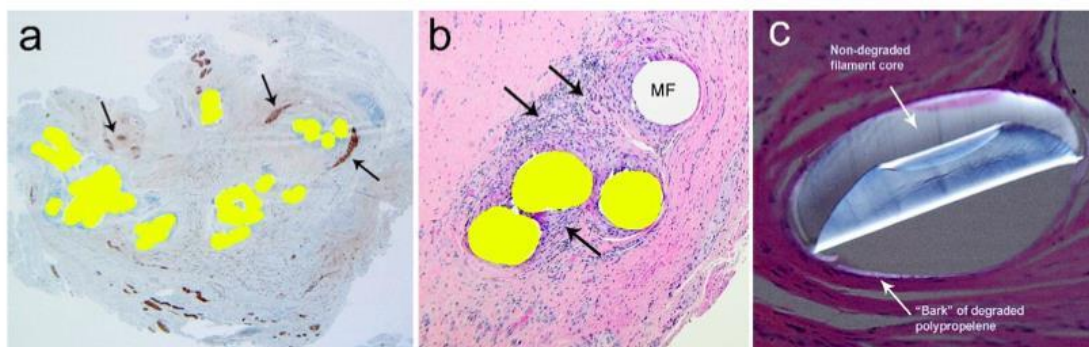


Figure 1. a: Nerve ingrowth. 2.5x objective, S100 stain to highlight nerves (dark brown, some nerves pointed by arrows). Mesh filaments are filled yellow for demonstration. **b:** Foreign body and non-specific chronic inflammation. H&E stain, 20x objective, three filaments filled yellow, one left unfilled (MF), inflammation pointed by arrows. **c:** Polypropylene degradation. 40x objective, partially polarized light. The bark of degraded polypropylene surrounds the central core (in the picture the core detached and folded). Both, the core and the bark show the same polarizing properties (brightly lit). The bark absorbs histological dyes due to its porosity and stains purple while the core remains clear (MF filament left clear in panel "b").

muscles may cause pain or defecatory dysfunction including constipation or incontinence of flatus or stool. Intraoperative nerve damage presents immediately following the procedure. Sharp pain in a specific nerve distribution presenting in the immediate postoperative period suggests intraoperative nerve damage and should be treated.

“Nerve pain that presents in the postoperative period and persists into the delayed postoperative period should be considered an example of mesh pain and trigger evaluation for other etiologies as well. This includes nerve entrapment and the pelvic organ cross-talk or sensitization. Posterior compartment repair may cause injury to the lumbosacral plexus, sciatic nerve, or pudendal nerve.”³²

Chronic mesh pain syndrome (CMPS) is reported in the medical literature and refers to a complex condition that develops in some patients with pain following mesh reconstruction. This pain persists beyond the routine postoperative period and is characterized by its intensity. It is also refractory to medical and surgical treatment. Regional and systemic symptoms develop as a result of nerve up-regulation, cross-talk and central sensitization. CMPS is a pathologic condition caused by the transformation of local vaginal pain into a multiorgan systemic process.³³

The potential for serious pain conditions resulting from the transvaginal mesh should have been apparent from the experience of hernia mesh in the abdominal wall and elsewhere in the body. Chronic pain is the most serious long-term complication that can occur after repair of groin hernia. The incidence of chronic pain after herniorrhaphy has been reported to be 30% or even higher. The complaint of chronic pain after inguinal hernia repair continues for months or even years. The development of chronic pain has been attributed to several mechanisms, including damage to sensory nerves and mesh inguinodynia.

In my opinion a medical device that injures and entraps nerves and muscle, sometimes resulting in chronic, severe, and intractable pain conditions, is flawed.

6. Because of the unique design of the pelvic organ system, Ethicon’s transvaginal mesh devices can result in bowel problems, bladder problems, and sexual dysfunction.

The vagina is a dynamic organ that must respond to motion and dynamic changes in adjacent organs (bowel and bladder) and with sexual relations. The space is shared and confined between all the pelvic organs and they need to move in relation to one another.

If nerves and muscles are present and are functioning properly, the pelvic floor is a versatile dynamic structure with the possibility of fine regulation of muscle activity. The innervation of the lower urinary tract is complex and includes sensory and motor functions as well as somatic and autonomic systems. The urethra is like the mouth or the larynx, innervated by the right and left. Motor neurons and muscle fibers are arranged in independent functional units called motor units, and a limited number of motor units are responsible for muscle control. The greater the number of motor neurons to the urinary sphincter, the greater the number of motor units, and the more versatile the range of possible muscle activity. Conversely, the lesser the number of motor neurons, the less versatile or more clumsy the possible range of sphincter activity. Patients with neurologic

³² Rogo-Gupta (2013).

³³ Rogo-Gupta (2013).

deficits in the pelvis may demonstrate irritative bladder symptoms and variable degrees of voiding difficulty and dysfunction.

Anorectal and bowel problems, likewise, are mediated by a complex arrangement of nerves and muscles in the pelvis. The normal act of defecation is easy and complete. The bowel should function with the effortless displacement of the stool from the lower bowel. After normal defecation, the sigmoid colon and rectum are empty and the stool is gone. If there is impairment of the nerves and muscles of the lower bowel, the function is more likely to be incomplete, and instead of the train leaving the station, only one or two cars might leave, but the bulk of the train continues to stand. The rectum and sigmoid colon remain loaded with stool most of the time. Constipation, diarrhea, irritable bowel symptoms, and pain can be associated with the loss of versatile sphincter and pelvic floor function.

Shared nerves means shared behaviors, and Kaplan et al. described this phenomenon as “crosstalk”, the functional relationship between bladder and bowel. “The connection between bladder and bowel function is apparent in several clinical disorders, including chronic pelvic pain syndromes, urinary and faecal incontinence, organic diseases involving the colon, functional bowel disorders and OAB.”³⁴

In my opinion, a device designed for treatment of SUI or POP that invites widespread bladder, bowel and sexual dysfunction is flawed.

7. A permanent device that cannot be removed when complications dictate is unacceptable.

The medical literature contains numerous reports describing the difficulties and less than satisfactory outcomes associated with mesh removal. Those of us who are performing these surgeries on a regular basis know all too well the challenges of explant surgery. Putting mesh in is relatively easy. Taking it out is another matter. These surgeries are time-consuming, complicated, and risky for the patient. We never know what we will encounter until we get to the operating room. The anatomy is often distorted and healthy tissue often has to be removed along with the mesh. In many instances, it is impossible to remove the entire device. We are always concerned about the possibility of doing more harm than good. This is an entirely different situation from the treatment of any other surgical complication.

Rogo-Gupta described the technically challenging removal of armed mesh. “To successfully remove armed mesh segments in their entirety, the obturator membrane must be perforated and dissection carried out laterally. Additional incisions in the thighs may be required to adequately free the arms from the surrounding soft tissues. We suggest preoperatively marking the lateral puncture sites to facilitate intraoperative dissection. If the lateral incisions cannot be identified by patient symptoms or scarring, gentle traction on the medial portion of the mesh arms may be used as a guide. The mesh should be followed from skin incision to the intersection of the adductor muscles and dissected free in a circumferential fashion. Muscle fibers often must be dissected when mesh has become incorporated into the surrounding fibers. Large defects in the vaginal wall may occur with mesh removal and surgeons ought to be prepared to utilize rotational vaginal flaps,

³⁴ Kaplan, S. A., Dmochowski, R., Cash, B. D., Kopp, Z. S., Berriman, S. J., & Khullar, V. (2013). Systematic review of the relationship between bladder and bowel function: implications for patient management. *Int J Clin Pract*, 67(3), 205-216. doi: 10.1111/ijcp.12028

labial flaps, or skip flaps for reconstruction. Following complete healing and resolution of other symptoms such as pain, infection, bleeding, urinary or defecatory dysfunction, evaluation for additional surgery for persistent incontinence or prolapse can begin if clinically indicated.”³⁵

Reynolds et al. reported a series of patients in which obturator dissection was performed via a lateral groin incision over the inferior pubic ramus at the level of the obturator foramen, typically in conjunction with orthopedic surgery. All the patients in the series presented with “recalcitrant and devastating” groin pain after a transobturator sling procedure (5% to 16% of patients). According to the authors, “Groin pain after transobturator procedures is believed to be related to obturator nerve damage or entrapment and to resulting neuropathy. In addition, it may be nonneural in origin, and related to tension between the mesh material and adductor tissues.” In transobturator procedures, the “trocar and mesh penetrate several muscles and structures of the inner thigh and pelvis, including (in order from external to internal) the gracilis muscle, adductor brevis muscle, obturator externus muscle, obturator membrane, obturator internus muscle and periurethral endopelvic connective tissue.” Intraoperatively, the mesh was typically “closely associated to or traversing the adductor longus muscle and tendon insertion with significant fibrous reaction in all cases, and in 1 case the mesh was intimately associated with the obturator neurovascular bundle.” The authors noted the dispute over the best timing for removal of a sling when pain develops postoperatively, an issue should have been resolved before marketing a device.³⁶

Barber reported that the rate of requiring additional surgery for mesh complications is almost 50% in some series and seems to be higher in those undergoing partial excision at the initial operation. Recurrent pelvic organ prolapse was noted in 29% after complete excision and 5% of partial excisions. Dr. Barber described the removal of mesh for vaginal contraction, pain and dyspareunia, “If tenderness is focal and associated with a clearly defined contraction band, typically a lateral mesh arm, then transection of the contraction band without excision of the remaining mesh may provide adequate pain relief. If the tenderness is not localized or if release of the contraction band is not successful, then complete excision of the intra-vaginal portion of the mesh should be performed. This is done using the same technique as described previously for vaginal mesh exposure. The mesh arms should be transected as lateral as possible and all contraction bands released.”³⁷

Blandon also detailed the challenges of removal surgery. “The vaginal surgeon is faced with the challenges of very complex surgical dissections. If mesh excision is warranted, tissue fibrosis, scarring, bleeding, and urinary tract and anorectal injury are easily encountered, which add to patient morbidity...Moreover, whereas minor complications such as small vaginal mesh erosions are simple and easy to manage, incapacitating pelvic pain, dyspareunia, and large-scale erosions can be exceedingly complex and not easily resolved.”³⁸

³⁵ Rogo-Gupta, 2013.

³⁶ Reynolds, W. S., Kit, L. C., Kaufman, M. R., Karram, M., Bales, G. T., & Dmochowski, R. R. (2012). Obturator foramen dissection for excision of symptomatic transobturator mesh. *J Urol*, 187(5), 1680-1684. doi: 10.1016/j.juro.2011.12.065

³⁷ Barber, M. D. (2013). Surgical techniques for removing problematic mesh. *Clin Obstet Gynecol*, 56(2), 289-302. doi: 10.1097/GRF.0b013e3182856371

³⁸ Blandon, R. E., Gebhart, J. B., Trabuco, E. C., & Klingele, C. J. (2009). Complications from vaginally placed

Crosby et al. at the University of Michigan, Ann Arbor, recently reported a 10-fold rise in the number of vaginal mesh removals in the past five years. The authors found that removal of vaginal mesh was helpful in relieving presenting symptoms, but complete resolution of symptoms, especially pain or dyspareunia, occurs in less than half of patients following excision.^{39 40} Hartshorn also reported on mesh complications as an increasingly common indication for referral to tertiary care centers.⁴¹ Pain resulting in deterioration of sexual function is a common symptom that is often managed by surgical removal of mesh. Based on this sample, surgical removal of mesh does not appear to improve pain related to sexual activity or overall sexual function. This has significance in the preoperative counseling of patients who are candidates for removal of transvaginal mesh.

My experience confirms the difficulty and often impossibility of removing the entire mesh product. Because of the location of mesh devices, tissue ingrowth, inflammation, and scar plate, removal surgery is often risky and complex. In most instances, remnants of mesh or mesh fibers are left behind. Multiple procedures may be required and results are often less than optimal, particularly when the mesh devices are removed for pain.

8. A literature review of transvaginally placed surgical meshes raises serious concerns about the safety and efficacy of these products for prolapse repair.

A product may be defective if the risks do not outweigh the benefits or is “not reasonably safe.” Mesh kits for pelvic organ prolapse and SUI offer no benefits over traditional repairs.

The initial studies on efficacy of POP mesh kits seemed to demonstrate an anatomic improvement in the anterior compartment. These studies can now all be discredited for various reasons. There were never any benefits identified in the apical or posterior compartment, any reduction in reoperations for recurrent prolapse, or any improvement in Quality of Life measurements. In the past couple of years, several papers have re-looked at the efficacy of native tissue repairs as compared to TVM procedures and found no improvements in efficacy.

The double-blinded randomized controlled trial initiated by Iglesia was halted because of excessive erosion, recently reported 3-year data on efficacy. Sokol and the other authors found cure rates and satisfaction after prolapse repair with and without mesh were high based on absence of prolapse beyond the hymen, lack of bulging symptoms and global impression of improvement (PGI-I).⁴² This study draws into question the long-term value of vaginal mesh compared to native

mesh in pelvic reconstructive surgery. *Int Urogynecol J Pelvic Floor Dysfunct*, 20(5), 523-531. doi: 10.1007/s00192-009-0818-9

³⁹ Crosby, E. C., Berger, M. B. DeLancey, I.L., Fenner, D.E. & Morgan, D. M. (2012). Symptom resolution after operative management of complications from vaginal mesh. *Female Pelvic Medicine & Reconstructive Surgery*, 18 (5), 2

⁴⁰ Crosby, E.C., Abernethy, M., Berger, M.B., DeLancey, J.O., Fenner, D.E., Morgan, D.M. (2014). Symptom Resolution After Operative Management of Complications From Transvaginal Mesh. *Obstet Gynecol*, 123(1), 134-139

⁴¹ Hartshorn, T.G., Rogo-Gupta, L., Tarvay, C.M., Rodriguez, L.V. & Raz, S. (2012). Sexual function after surgical removal of transvaginal mesh. *AUGS*, Poster Presentation 35.

⁴² Iglesia, C. B., Sokol, A. I., Sokol, E. R., Kudish, B. I., Gutman, R. E., Peterson, J. L., & Shott, S. (2010). Vaginal mesh for prolapse: a randomized controlled trial. *Obstet Gynecol*, 116(2 Pt 1), 293-303. doi: 10.1097/AOG.0b013e3181e7d7f8

tissue repairs. Subjects in the mesh group suffered complications unique to vaginal mesh without long-term benefit as there was no perceived difference in success.

Stanford reviewed the literature on the success of traditional/native tissue success versus mesh-augmented repairs and found the “overall success rates of NT and MA repairs when recurrent prolapse is the primary outcome measure are very similar.”⁴³ Oversand also found POP surgery using native tissue repair entails low reoperation rates with excellent subjective and objective results, few complications and should be the first choice in treating primary POP.⁴⁴ Funk and Visco analyzed 27,809 prolapse surgeries from an insurance database. The authors “found evidence that the use of mesh for anterior vaginal wall prolapse was associated with an increased risk of any repeat surgery, which was driven by surgery for mesh removal. Vaginal mesh and native tissue repair for anterior prolapse had similar 5-year risks for recurrent prolapse.”⁴⁵

I have reviewed the reliable scientific literature regarding the use of transvaginal mesh for prolapse repair. From these studies (and confirmed by my clinical experience), I have made the following conclusions regarding the efficacy of these products:

There is no good evidence supporting benefit in quality of life (QOL) or relief of symptoms in any compartment with the use of trans-vaginal mesh for the treatment of POP. A recent study of 27,809 anterior prolapse surgeries with 49,658 person- years of follow-up determined that native tissue and vaginal mesh surgery had similar 5-year risks for surgery for recurrent prolapse.⁴⁶

There is no reduction in reoperation rates for prolapse in any compartment with the use of trans-vaginal mesh for the treatment of pelvic organ prolapse. There is no evidence of anatomic benefit with the use of trans-vaginal mesh for the treatment of POP in the posterior or apical compartments.

There are studies that suggest anatomic benefit in the anterior compartment only, but this finding has limited, if any, clinical significance. Other studies show no anatomic benefit. Recent studies indicate that the anatomic benefits (anterior compartment only) suggested in earlier trials are unfounded and the result of bias.

The total number of reoperations is higher in mesh repairs due to the rate of surgeries for repair of complications.

I have made the following conclusions regarding the safety of these products from my review of the scientific literature:

⁴³ Stanford, E. J., Cassidenti, A., & Moen, M. D. (2012). Traditional native tissue versus mesh-augmented pelvic organ prolapse repairs: providing an accurate interpretation of current literature. *Int Urogynecol J*, 23(1), 19-28. doi: 10.1007/s00192-011-1584

⁴⁴ Oversand, S. H., Staff, A. C., Spydslaug, A. E., Svenningsen, R., & Borstad, E. (2013). Long-term follow-up after native tissue repair for pelvic organ prolapse. *Int Urogynecol J*. doi: 10.1007/s00192-013- 2166-z

⁴⁵ Funk, M. J., Edenfield, A. L., Pate, V. & Visco, A. G. Trends in mesh use between vaginal prolapse repair and sacrocolpopexy, 2005-2010. *Female Pelvic Medicine & Reconstructive Surgery*, 18 (5), 2.

⁴⁶ Funk, M. J., Levin, P. J., & Wu, J. M. (2012). Trends in the surgical management of stress urinary incontinence. *Obstet Gynecol*, 119(4), 845-851

1. Adverse events and complications are common.
2. Many of these complications do not occur with traditional prolapse repairs.
3. Many of these complications are life-altering and permanent, unlike those seen with traditional prolapse repairs. Many of these complications require additional surgery, which may or may not alleviate the symptoms - unlike traditional prolapse repairs.
 - The study noted above with 27,809 anterior prolapse surgeries with 49,658 person-year of follow-up determined that the use of mesh for anterior prolapse was associated with an increased risk of any repeat surgery, which was driven by surgery for mesh removal.⁴⁷
 - These complications can occur at any time, unlike complications occurring with traditional prolapse repairs.
 - Explant surgery, when indicated, is risky, difficult to perform, and may or may not alleviate symptoms.

I have concluded the following regarding the differences regarding the mesh complications and those associated with traditional surgery:

- Many of the complications reported occur only with mesh. These include erosion and extrusion, mesh contraction syndrome, organ perforation from mesh, partner injury, severe vaginal pain, granulomas, and need for multiple surgical procedures for removal and attempted relief of pain.
- Mesh complications, as opposed to complications with traditional repairs, are likely to be more frequent and more severe. Examples include dyspareunia, de novo stress urinary incontinence, chronic pelvic pain, neuromuscular injury, and emotional sequelae.
- Most mesh complications are more difficult to treat. This includes fistulae, bleeding, infection, bowel/bladder injuries, dyspareunia, pelvic pain, and recurrent prolapse.
- The potential for complications lasts indefinitely because the synthetic mesh is permanent.
- Some risks are still unknown and cannot be known for many years to come.

Similar literature is available for SUI. Synthetic slings are no more effective than traditional Burch procedure or autologous slings and create unique and, sometimes severe complications.⁴⁸ For

⁴⁷ Funk, 2012

⁴⁸ Albo ME, Richter HE, Brubaker L, Norton P, Kraus S, et. al.; Burch colposuspension versus fascial sling to reduce urinary stress incontinence; New England Journal of Medicine 2007;356:2143-2155; Amaro, J. L.,

example, in a randomized controlled trial by Amaro, satisfaction rates were 62.5 to 97.5% in AFS group, while in TVT group it was between 36 to 80%. In this study, AFS and TVT yielded similar results, except for operating time which was shorter in TVT.⁴⁹ Chapple recommended that when a patient has made the decision to proceed with surgery, alternative surgical options that include non-mesh-based techniques should be offered, such as an autologous fascial sling or bladder neck suspension.⁵⁰

In a recent review article published in *Nature*, one of the most prestigious journals in the world, Blaivas described the complications associated with synthetic mesh slings. The most common risks in patients with SMUS include urethral obstruction requiring surgery (2.3% of patients with SMUS), vaginal, bladder and/ or urethral erosion requiring surgery (1.8%) and refractory chronic pain (4.1%). At least one third of patients developed recurrent SUI, based on the review. Additionally, complications are under-reported. The authors provide an excellent discussion of the mechanisms by which synthetic slings produce complications – all based on peer-reviewed, reliable medical literature.⁵¹

Both the American College of Obstetrics and Gynecology and the American Urology Association endorse the use of autologous slings and Burch procedure.⁵²

Recent literature is finally addressing the long-term consequences of vaginal mesh complications and the outcomes of attempts at surgical treatment - reporting large numbers of patients in academic medical centers like Emory. This reflects the lag time between the appreciation of these devastating complications for those of us in a referral practice and awareness by community physicians. These studies show a significant number of women who fail to respond to treatment despite the best care available and remain in worse condition than they were before having the

Yamamoto, H., Kawano, P. R., Barros, G., Gameiro, M. O. O., & Agostinho, A. D. (2009). Clinical and quality-of-life outcomes after autologous fascial sling and tension-free vaginal tape: a prospective randomized trial. *Int Braz J Urol*, 35:60-67; Birch, C., & Fynes, M. M. (2002). The role of synthetic and biological prostheses in reconstructive pelvic floor surgery. *Curr Opin Obstet Gynecol*, 14(5), 527-535; Blaivas, J. G., & Chaikin, D. C. (2011). Pubovaginal fascial sling for the treatment of all types of stress urinary incontinence: surgical technique and long-term outcome. *Urol Clin North Am*, 38(1), 7-15, v. doi: Blaivas, J. G., Purohit, R. S., Weinberger, J. M., Tsui, J. F., Chouhan, J., Sidhu, R., & Saleem, K. (2013). Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications. *J Urol*. doi: 10.1016/j.juro.2013.03.044; Brown, S. L. & Govier, F. E. (2000). Cadaveric versus autologous fascia lata for the pubovaginal sling: surgical outcome and patient satisfaction. *The Journal of Urology*, 164:1633- 1637; Broussard, A. P., Reddy, T. G., Frilot II, C. F., Kubricht III, W. S., & Gomelsky, A. (2013). Long-term follow-up of porcine dermis pubovaginal slings. *Int Urogynecol J*, 24:583-587; Brubaker, L., Richter, H.E., Norton, P.A., Albo, M., Zyczynski, H.M., Chai, T.C., Zimmern, P., Kraus, S., Sirls, L., Kusek, J.W., Stoddard, A., Tennstedt, S., Gormley, A. (2012). 5-Year Continence Rates, Satisfaction and Adverse Events of Burch Urethropexy and Fascial Sling Surgery for Urinary Incontinence. *J Urology*, 187: 1324- 1330, 10.1016/j.ucl.2010.12.002

⁴⁹ Amaro, J. L., Yamamoto, H., Kawano, P. R., Barros, G., Gameiro, M. O. O., & Agostinho, A. D. (2009). Clinical and quality-of-life outcomes after autologous fascial sling and tension-free vaginal tape: a prospective randomized trial. *Int Braz J Urol*, 35:60-67

⁵⁰ Chapple, C. R., Raz, S., Brubaker, L., & Zimmern, P. E. (2013). Mesh Sling in an Era of Uncertainty: Lessons Learned and the Way Forward. *Eur Urol*. doi: 10.1016/j.eururo.2013.06.045

⁵¹ Blaivas, et al., Safety considerations for synthetic sling surgery, *Nat. Rev. Urol.* advance online publication 18 August 2015; doi:10.1038/nrurol.2015.183

⁵² ACOG Practice Bulletin Number 155, November 2015; Dmochowski et al. At least one-third of patients undergoing sling excision surgery develop recurrent SUI. Update of AUA Guideline on the Surgical Management of Female Stress Urinary Incontinence *J Urol* 183, 1906-1914, May 2010

initial operation.⁵³

I am not aware of any other surgical procedure that has created a “new disease” such as that we are seeing since the introduction of trans-vaginal mesh. It has even been given a name in the recent literature, “Meshology.”⁵⁴

In my opinion, the risks of polypropylene mesh in vaginal prolapse and SUI repairs outweigh the benefits.

IV. DISCUSSION OF FINDINGS REGARDING PLAINTIFF

Ediany Carbon v. Ethicon, Inc., et al.

Case No. 2:12-cv-04269

Implanting Surgeon: ALAN R. SCHNEIDER, MD HOLY CROSS HOSPITAL,
4725 NORTH FEDERAL HIGHWAY, FORT LAUDERDALE, FLORIDA 33308

Date of Mesh Implants January 7, 2008

Products:

1. Gynecare Anterior Prolift Pelvic Floor System PFRT01 Lot # 3028206
2. TVT-Secur Lot # 3017987

Surgical Revision Procedures:

- 1. 7/17/2008, partial excision of the Prolift mesh - Dr. Schneider**
- 2. 8/18/2009, second revision mesh excision surgery (1) excision of eroded sling at pubic ramus; and (2) excision of eroded mesh at the anterior cervical fornix. 1 cm piece of the TVT-Secur was removed - Dr. Vivian Aguilar, Cleveland Clinic**
- 3. 3/5/2013, third revision surgical procedure to remove mesh bands from her prior Prolift and removal of mesh fibers from the extruded TVT-S sling - Dr. Vivian Aguilar, Cleveland Clinic**
- 4. 12/12/2018 - fourth revision surgical procedure to remove mesh: 1) Anterior/apical vaginal mesh removal and 2) Anterior repair for vaginal pain and vaginal mesh exposure Eric A. Hurtado, MD, Cleveland Clinic.**

In Office Treatments for eroded mesh:

⁵³ e.g. Hammett, J., et al. (2014). "Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery." *Int Urogynecol J* 25(4): 465-470; Dunn, G. E., et al. (2014). "Changed women: the long-term impact of vaginal mesh complications." *Female Pelvic Med Reconstr Surg* 20(3): 131-136; Hansen, B. L., et al. (2014). "Long-term follow-up of treatment for synthetic mesh complications." *Female Pelvic Med Reconstr Surg* 20(3): 126- 130; Abbott, S., et al. (2014). "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study." *Am J Obstet Gynecol* 210(2): 163 e161-168; Unger, C. A., et al. (2014). "Outcomes following treatment for pelvic floor mesh complications." *Int Urogynecol J* 25(6): 745-749;

⁵⁴ Lee et al., *Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes*, *Expert Rev. Med. Devices* Early online, 1–16 (2014)

- 8/27/2008, Silver nitrate was applied
- 9/26/2008, Silver nitrate was applied
- 10/24/2008, Silver nitrate was applied
- 1/14/2009, Excision of mesh and Monsel's solution applied (Schneider)
- 2/11/2009, Silver nitrate and Monsel's solution applied
- 3/4/2009, Silver nitrate and Monsel's solution applied
- 3/18/2009, Silver nitrate and Monsel's solution applied
- 3/31/2009, Schneider saw mesh erosion and applied more Monsel's solution
- 4/10/2009, Schneider saw mesh erosion and applied more Monsel's solution
- 4/17/2009, Schneider saw mesh erosion and applied more Monsel's solution
- 4/23/2009, Schneider saw mesh erosion and applied more Monsel's solution
- 5/1/2009, Schneider saw mesh erosion and applied more Monsel's solution

Medical Chronology:

Mrs. Ediany Carbon (dob [REDACTED]) has a medical history significant for herpes simplex, hypertension, vitamin D deficiency, TMJ, right paracervical pain with radiation to the upper right trapezius, hypercholesterolemia, mastodynia, finger and elbow joint pain and preeclampsia. She is married, a non-smoker, gravida 1, vaginal delivery 1, weighing 5.10 lbs.

On November 29/2007, Mrs. Carbon presented to Dr. Schneider at the age of 38 with urinary complaints and pelvic discomfort. "Patient has had symptoms of OAB/IC since birth of her child in 2005. Her PCP put her on Detrol, which has helped. Her gynecologist has recommended urodynamic evaluation. Patient has c/o urinary frequency and urgency, nocturia x2, slow stream at times and **mild stress incontinence**. She also has c/o bloating and suprapubic pressure and history of 1-2 UTI's per year." A negative Marshall test was documented.

Dr. Schneider proposed cystoscopy and urodynamic testing.

On December 10/2007, Cystoscopy revealed moderate trigonitis and grade I cystourethrocele.

On December 13/2007, urodynamics revealed a stable compliant bladder of large capacity and normal sensation.

On December 26/2007, Mrs. Carbon returned to discuss the test results. Dr. Schneider recommended pelvic floor repair and mid-urethral sling.

On January 7/2008, Mrs. Carbon had surgery.

Operative note records Preoperative Diagnoses as 1. Cystourethrocele 2. Urinary urgency, frequency 3. Pelvic discomfort and 4. Mild stress incontinence.

Surgery included transvaginal placement of Gynecare Anterior Prolift Pelvic Floor System and a TVT-Secur. Dr. Schneider noted, "the entire mesh (Prolift) was then laid out smoothly on the cystocele." No complications or deviations from the standard of care were noted.

On January 15/2008, Mrs. Carbon had a postop visit. Complaints included pain and discomfort in the clitoral meatus area. Physical examination revealed good support with healed incisions.

On February 21/2008, at 6-week post-op visit, an area of **mesh erosion anterior to the cervix 1-3cm horizontal was noted**. Dr. Schneider recommended continued use of estrogen cream.

On March 20/2008, Mrs. Carbon returned for follow up. The progress note included she had "intercourse without problems". The area of **mesh erosion anterior to cervix 1-2 cm** was "improved".

On April 14/2008, Mrs. Carbon returned with new complaints of urinary incontinence, urinary/pelvic discomfort. Examination revealed **the area of mesh erosion anterior to cervix 2-3cm "aggravated"**. Dr. Schneider recommended continued use of estrogen cream and if not improved in 6 weeks, would schedule Mrs. Carbon for outpatient surgical mesh excision and repair.

On May 28/2008, Mrs. Carbon returned with continued discomfort and stated she could **feel mesh**. The mesh erosion was now noted to be 3 cm.

On July 17/2008, Mrs. Carbon returned to the operating room for partial excision of the Prolift mesh. **Dr. Schneider identified "the proximal edge of the anterior Prolift mesh through a vaginal ulcer near the anterior cervical fornix. The erosion was approximately 2.5cm x .5cm in width."**

After surgery, Mrs. Carbon continued to experience vaginal and pelvic pain and had vaginal bleeding. She complained of dyspareunia and reported being "barely sexually active". Mrs. Carbon reported frequency and urgency.

On August 6/2008, Mrs. Carbon followed up with Dr. Schneider having persistent vaginal discharge. Examination revealed, vaginal cuff healing well, negative for erythema or mesh noted.

On August 27/2008, further examination revealed a **new area of mesh erosion** on patient's right side posterior vaginal wall fornix. **Silver nitrate** was applied.

On September 26/2008, Mrs. Carbon returned again with complaints of vaginal discomfort and lower back pain. Examination confirmed **mesh erosion on right vaginal wall**. **Silver nitrate** was applied. **Diagnosis included bacterial vaginosis**.

On October 7/2008, the vaginal discharge and itching had worsened when seen again by Dr. Schneider.

On October 24/2008, symptoms included low back pain and supra-pubic pressure also persistent yellow/white vaginal discharge. **Silver nitrate** was applied to the **persistent erosion**. Dr. Schneider prescribed a course of antibiotics.

On November 25/2008, the vaginal discharge had improved and she was sexually active. Examination did not reveal mesh erosion.

On December 10/2008, the vaginal discharge had returned and Mrs. Carbon could feel mesh in her vagina. New complaints included urinary incontinence, and urinary/pelvic discomfort. Examination revealed "**area of mesh or stitch** noted on her right side".

On January 14/2009 she returned to Dr. Schneider with a **vaginal mesh erosion**, continued urinary incontinence and urinary/pelvic discomfort. Dr. Schneider recorded that he **excised the mesh and Monsel's solution was applied in the office**.

On January 23/2009, Dr. Schneider called in another prescription of Diflucan for Mrs. Carbon.

On February 11/2009, Dr. Schneider identified a **mesh erosion** and applied more silver nitrate and Monsel's solution

On March 4/2009, Dr. Schneider identified a **mesh erosion** and applied more silver nitrate and Monsel's solution

On March 18/2009, Dr. Schneider identified **mesh erosion** and applied more silver nitrate and Monsel's solution.

On March 31/2009, Dr. Schneider identified **mesh erosion** and applied more Monsel's solution

On April 10/2009, Dr. Schneider identified **mesh erosion** and applied more Monsel's solution

On April 17/2009, Dr. Schneider identified **mesh erosion** and applied more Monsel's solution

On April 23/2009, Dr. Schneider identified **mesh erosion** and applied more Monsel's solution

On May 1/2009, Dr. Schneider identified **mesh erosion** and applied more Monsel's solution

On May 15/2009, Dr. Schneider recorded that Mrs. Carbon still had **mesh erosions at the vaginal apex 2cm and 8mm in size, despite treatments** with silver nitrate and Monsel's solution.

On June 9/2009 during urodynamic testing. Craig Herman, MD performed a vaginal examination, which revealed **palpable mesh exposed on the anterior vaginal wall** and recommended further mesh removal.

On July 16/2009, seeking a second opinion, Mrs. Carbon presented to Dr. Vivian Aguilar at the Cleveland Clinic Florida with complaints of sexual dysfunction, dyspareunia and recurrent infections. Examination revealed **mesh erosion at the vaginal apex anteriorly with granulation tissue**, muco-purulent discharge, another erosion distally at left edge of mesh near UVJ, mild vaginal atrophy, pain along vaginal erosion and mesh arms anteriorly. Dr. Aguilar prescribed estrogen cream and **recommended surgical intervention**.

On August 18/2009, Mrs. Carbon underwent a **second revision mesh excision** surgery at the Cleveland Clinic in Weston, Florida. Dr. Vivian Aguilar performed an (1) **excision of eroded sling at pubic ramus; and (2) excision of eroded mesh at the anterior cervical fornix. A 1 cm piece of the TVT-Secur was removed.** Attention was then turned to the anterior fornix. An eroded area measured approximately 3 cm x 3 cm. Cystoscopy revealed no intraoperative injury. Surgical pathology of **three segments of mesh material** with an aggregate measurement of 4.9 cm in greatest dimension was examined grossly.

After surgery, Mrs. Carbon's symptoms improved greatly, with some remaining mild tenderness noted at the left inferior border of the pubic ramus.

On January 12/2010, Mrs. Carbon returned to Dr. Aguilar in follow-up, 20 weeks post excision of the eroded sling at the pubic ramus and excision of eroded mesh at the anterior cervical fornix. She reported feeling something "artificial" in the vagina without bleeding, dyspareunia or erosion noted. Examination revealed the presence of a 1st degree cystocele and central rectocele.

On September 22/2010, at follow up visit with Dr. Aguilar, Mrs. Carbon reported return of dyspareunia and vaginal dryness. Examination failed to reveal evidence of erosion.

On January 21/2011, Mrs. Carbon presented to the Cleveland Clinic for her annual examination and reported occasional discomfort with intercourse. Estrogen vaginal cream was prescribed.

On August 31/2011 Mrs. Carbon was seen by Dr. Aguilar and reported a pulling pain in the vaginal area while exercising, pain in the right side of the vagina with intercourse and activity/exercise, vaginal dryness and dyspareunia. Dr. Aguilar attributed the dyspareunia to **vaginal mesh scar/nodule**. Urodynamic testing and possible surgery was recommended.

On February 10/2012, Mrs. Carbon returned in follow up with Dr. Aguilar, reporting continued vaginal pain and dryness. Examination revealed a small size inclusion cyst without any further mesh erosions or tender bands. Dr. Aguilar opined that Mrs. Carbon's current dyspareunia was collisional dyspareunia with the uterus and did not recommend further mesh removal at that time.

On November 29/2012, Mrs. Carbon returned stating that she has had an increase in urinary urgency and feels that she has more mesh coming through. She reported being sexually active and suffering dyspareunia. She denied vaginal dryness. Examination revealed no vaginal atrophy, but **mesh scarring and palpable mesh was present at the anterior fornix bilaterally, which reproduced the reported pain. Mesh erosion was present along with pain and tenderness immediately posterior to the pubic ramus.** Dr. Aguilar scheduled urodynamic testing.

On January 4/2013, urodynamic testing was done and revealed a normal study.

On March 5/2013, at the age of 43, Mrs. Carbon underwent a **third revision surgical procedure to remove mesh bands from her prior Prolift and removal of mesh fibers from the extruded TVT-S sling. Dr. Aguilar also performed a posterior colporrhaphy and cystoscopy. Intraoperative findings included bunched and scarred mesh at the left inner Prolift arm and extruded sling fibers.** Dr. Aguilar noted that preoperative physical examination was significant

for **mesh scarring which was tender and palpable at the anterior fornix bilaterally that reproduced the pain Mrs. Carbon was experiencing. Mesh erosion, tenderness and pain was identified** immediately posterior to the pubic ramus.

On March 20/2013, at follow up with Dr. Aguilar, she was somewhat improved since surgery, but had vaginal bleeding/discharge, buttock and perineal pain.

On April 17/2013, at six weeks post-op, Mrs. Carbon complained of vaginal bleeding/discharge and pelvic pressure. Examination revealed mild scarring from "so many prior surgeries."

On June 10/2013, at the next visit, Mrs. Carbon reported intermittent pelvic discomfort at the perineum, dyspareunia and vaginal dryness. Examination revealed no evidence of atrophy, but a small pea sized area of induration at the perineum.

On November 6/2013, Mrs. Carbon reported pinching during intercourse, dyspareunia and vaginal dryness.

On May 7/2014, at her annual visit, Mrs. Carbon reported persisting discomfort with intercourse. Examination revealed vaginal scarring at the lateral fornices and palpation reproduced the pain.

On June 1/2015, Mrs. Carbon's pelvic examination revealed an **area of granulation tissue on the right vaginal wall with tenderness**. At this visit Mrs. Carbon was also diagnosed with vaginitis.

On February 17/2017, Mrs. Carbon was seen again at the Cleveland Clinic for symptoms of worsening dyspareunia and a feeling of some poking on one side, vaginal dryness and pain in urethral area with yoga. Symptoms worse in the last month, also concerned she has recurrent prolapse. Examination by Dr Hurtado revealed **mesh exposure at the right lateral apex also pain and tenderness** at left obturator internus muscle. The vaginal apex was tender on the right and left, and an **anterior band was felt that corresponds with patient's pain**.

On February 24/2017, 3-D ultrasound study was done. **Retained mesh was identified**. Dr Hurtado discussed treatment options of repeat local excision of exposure and steroid injection or more radical excision.

"Options were reviewed with the patient. Patient is not interested in pursuing conservative therapy for her urogynecologic dysfunction and thus surgery will be performed. The risks including but not limited to pain, bleeding, infection, damage to surrounding structures, persistent/worsened incontinence, difficulty urinating/passing bowels, painful intercourse, recurrence, healing abnormalities, heart problems, lung problems, blood clots, and death were discussed with the patient. The need for any other indicated procedures were also discussed including conversion to an open procedure. After also discussing the benefits and alternatives, the patient desires to proceed with trigger point injection of left peri-urethral fascia, revision of apical mesh, trigger point of apex, and cystoscopy."

On December 12/2018, Mrs. Carbon had a **fourth vaginal mesh excision procedure. Dr. Hurtado at Cleveland Clinic performed 1) Anterior/apical vaginal mesh removal 2) Anterior**

repair and cystoscopy in an effort to help resolve persisting vaginal pain and recurrent vaginal mesh exposures.

Pathology specimen confirmed – **“Vaginal mesh” 4 X 1.7 X 0.5 cm** “white plastic mesh material”
- Gross only - no studies were done.

Immediate postoperative course was satisfactory. Discharged home on pain medications including Tylenol, Gabapentin, Ibuprofen and Oxycodone (opioid).

V. CASE SPECIFIC OPINIONS

Mrs. Ediany Carbon has experienced mesh-related complications including chronic persistent pelvic pain requiring long-term medications, mesh erosion, dyspareunia, urinary tract infections, vaginal pain, recurrence of incontinence, bladder and bowel dysfunction, nerve damage, and mesh extrusion leading to the need for four mesh removal surgeries. The cause of these complications can be directly attributed to the Gynemesh Prolift and TVT-S products. More likely than not, these injuries are the direct result of the defects inherent in the Gynemesh Prolift and TVT-S devices, including source of chronic inflammation, foreign body reaction, deformation, scarring and fibrosis, hardening, nerve damage, and degradation of the polypropylene mesh. These injuries were foreseeable based on experience with hernia mesh and the use of mesh in other pelvic applications.

Mrs. Ediany Carbon’s care and treatment met the prevailing standard of care (2008). Specifically, the implant operative note does not reveal any errors in surgical technique. In my experience, and supported in the medical literature, the “piecemeal” local excision of exposed mesh does not produce optimal outcomes. However, this is a common practice among physicians and Ethicon did not provide guidance on the management of complications for doctors using their products.

There were safer alternatives, including Burch procedure, paravaginal repair, colpopexy, native tissue repairs or autologous fascial sling that would have avoided the injuries experienced by Mrs. Carbon.

I performed a differential diagnosis to reach these conclusions. Exposure of mesh and erosion of mesh are unique complications of mesh. Mrs. Ediany Carbon did not have any significant pelvic pain issues prior to implantation of the vaginal Gynemesh Prolift and TVT-S products. The medical record reflects that prior to the mesh implantation she had no difficulties with intercourse.

Mrs. Carbon is a young woman and her prior health problems are few, but do include herpes simplex, hypertension, vitamin D deficiency, TMJ, hypercholesterolemia, mastodynia, and a history of preeclampsia; none of these problems have contributed to the vaginal mesh complications. Mrs. Carbon is not diabetic, has never had gynecologic or pelvic cancer, has never required pelvic irradiation or chemotherapy treatments and is a non-smoker.

Mrs. Carbon may be approaching peri-menopause. Like all women who are peri-menopausal, may have some degree of vaginal atrophy. Vaginal atrophy does not produce focal pain, vaginal induration, banding, scarring or other findings and is treatable with local estrogen. Other personal medical history including one vaginal delivery, right paracervical pain with radiation to the upper

right trapezius, finger and elbow joint pain and occasional back problems, and Mrs. Carbon's history of ovarian cysts and internal hemorrhoids do not explain the clinical course. Likewise, these are not the cause of her persistent chronic pelvic pain requiring daily analgesics nor the persistent vaginal symptoms and exam findings.

I reviewed the IFUs for the Gynemesh Prolift and TVT-S devices. In no way, do the IFUs describe the injuries experienced by Mrs. Carbon. The IFU does not provide information regarding the frequency, severity, lack of responsiveness to treatment, and permanence of complications associated with the product. It provides no guidance to doctors on ways to manage these complications. The implanting surgeon in this case did not display understanding about how to manage mesh exposure. In the first year after mesh placement, he performed twelve independent in office procedures on his patient Mrs. Carbon including attempted excision of mesh in the office, all in a vain effort to manage vaginal mesh exposures.

The IFUs misrepresent the material properties of polypropylene by describing "a minimum to slight inflammatory response, which is transient", a "deposition of a thin fibrous layer of tissue", and "soft and pliable". The IFUs also state that the mesh is not "subject to degradation or weakening by the action of tissue enzymes." The peer-reviewed scientific and medical literature clearly contradicts these statements.

The IFU incorrectly states that a "transitory local irritation at the wound site and a transitory foreign body reaction may occur". The IFUs also misrepresent the life changing and unique complications associated with trans-vaginally placed mesh devices by stating, "potential adverse reactions are those typically associated with surgically implantable materials". This is inconsistent with the medical literature and my clinical experience.

The IFUs do not address the potential for ongoing adverse events. It does not address the recalcitrant, persistent and recurrent nature of many vaginal mesh exposures and erosions suffered by Mrs. Carbon even years after mesh placement. The IFUs do not address the risk of permanent vaginal scarring and distortion, chronic pain, sexual impairment, and dyspareunia. The IFUs do not inform physicians of the difficulty and risks involved in removing these devices, the need for multiple surgeries, or the failure of surgery to correct the problems in many cases.

Dr. Schneider, the implanting surgeon was aware of the initial complications of pelvic pain, recognized the vaginal mesh erosion and in addition to in office treatments, performed the first of four vaginal mesh excisions performed under general anesthetic for exposed vaginal mesh. When complications persisted, Mrs. Carbon sought help from other healthcare providers and found her way to the Cleveland Clinic, a tertiary referral center, for further care.

This case reflects a very common feature of mesh complications, that problems typically occur years after implantation; the medical literature is burgeoning with reports of single center series with only short term follow up and these "research studies" by definition are blind to late and long-term patterns of complication. This may help to explain why the private practitioners have been so much slower than academic pelvic surgeons to recognize the inherent dangers of vaginal mesh design.

Mrs. Carbon's prognosis is guarded due to the chronicity of her symptoms and the persistence of her chronic vaginal and pelvic pain. She might still have remaining residual mesh fragments - in spite of four attempts to surgically remove the mesh - and it is likely that she will require additional medical, and possibly surgical treatment to address ongoing chronic pelvic pain and other symptoms, including dyspareunia, urinary tract infections, vaginal pain, bladder and bowel problems, recurrence of incontinence and nerve damage.

In my opinion, to a reasonable degree of medical certainty, the Ethicon's Gynemesh Prolift and TVT-S devices used in Mrs. Carbon were unreasonably dangerous because the risks far outweighed the benefits, Ethicon did not warn doctors and patients of the serious risks, and Ethicon made inaccurate and misleading representations as to its safety. It was unreasonably dangerous because Ethicon did not provide Mrs. Carbon or her doctors with accurate and complete information and warnings. Finally, claims made by Ethicon regarding the product's performance that were known to be misleading or untrue make the product unreasonably dangerous.

All my opinions are made to a reasonable degree of medical certainty. In formulating my opinions in this case, I have reviewed and considered the following medical records, depositions, reports, consultations and documents that relate specifically to Mrs. Carbon:

- Vivian C. Aguilar, M.D. - Deposition transcript and exhibits
- Ediany Carbon – Deposition transcripts and exhibits (December 30, 2016 and August 8, 2019)
- Alan Schneider, M.D. – Deposition transcript and exhibits
- Cleveland Clinic – Medical records
- Holy Cross Hospital – Medical records
- Eric Hurtado, M.D. – Medical records
- Alan Schneider, M.D. – Medical records
- Vivian Aguilar, M.D. – Medical records
- Urology Center of Florida – Medical records
- 21st Century Oncology d/b/a Lauderdale Urology Associates – Medical records
- Health Watch for Women, Inc. and Dr. Kenneth Kassin, M.D. – Medical records
- Craig William Herman, M.D. – Medical records
- South Florida ENT Associates, P.A. and Kendall Lisa Hanft, M.D. – Medical records
- Jorge Calle Medina, M.D. – Medical records
- Dr. John Watson – Medical records
- Roger Lefevre, M.D. – Medical records
- Quest Diagnostics Incorporated – Medical records

I reserve the right to amend or supplement these opinions based on new information, additional facts, or examination findings.

In addition to my curriculum vitae attached as Exhibit A. My reliance list is attached Exhibit B. My testimony list is attached as Exhibit C and my fee schedule is attached as Exhibit D.

A handwritten signature in black ink, appearing to read 'Niall T M Galloway'. The signature is fluid and cursive, with a long horizontal stroke at the end.

Niall T M Galloway, MB, FRCS

August 18th, 2019

EXHIBIT "A"

**EMORY UNIVERSITY SCHOOL OF MEDICINE
CURRICULUM VITAE**

Revised: June 2019

1. Niall Thomas McLaren Galloway
2. The Emory Clinic, Department of Urology, 1365 Clifton Road, NE, Atlanta, GA. 30322
Telephone, (404) 778-4898, Fax: (404) 778-4006.
3. Email address: ngallow@emory.edu
4. DOB: [REDACTED]
5. Citizenship: US Citizen
6. Current Titles and Affiliations: Associate Professor of Surgery/Urology, Emory University School of Medicine Medical, Director of the Emory Continence Center, Head of the Section of Neurourology, Urodynamics and Reconstructive Urology
 - a. Academic appointments:

1974 - 1975	Western General Hospital and Royal Infirmary of Edinburgh - Edinburgh, Scotland Internship
1975 - 1976	University of Edinburgh - Edinburgh, Scotland Tutor/Demonstrator of Anatomy
1976 - 1980	Royal United Hospital - Bath, England Resident in Surgery
1980 - 1982	Deaconess Hospital - Edinburgh, Scotland General Surgical Registrar
1982 - 1984	University of Edinburgh, Western General Hospital Edinburgh, Scotland Lecturer in Surgery/Urology
1984 - 1986	University Hospital of Wales, Cardiff and Cardiff Royal Infirmary - Cardiff, Wales Senior Registrar in Urology
1986 - 1987	Duke University Medical Center Durham, North Carolina USA Fellow, Urologic Surgery
1987 - 1988	Duke University Medical Center Durham, North Carolina USA Visiting Assistant Professor, Urology

1989 - 1997	Emory University & The Emory Clinic Atlanta, Georgia USA Assistant Professor of Urology Head of Section of Neurourology Urodynamics and Reconstructive Surgery
1991	Co-founder of Emory Continence Center with Lewis Wall of Gynecology
1997 - present	Associate Professor of Surgery (Urology)
2006 -	Membership and privileges at Emory Crawford Long Hospital in the Department of Surgery/Urology.

b. Primary appointments:
Medical Director of Emory Continence Center

7. Previous Academic and Professional Appointments:

Post Graduate Medical Education - Teaching
Director of Post Graduate Seminar - Emory University
"Surgical Management of Complex Continence Problems" 1990

Director of "Advances in the Treatment of Incontinence"
Emory University, November 3-4, 1995.

Director of "Advances in the Treatment of Incontinence"
Emory University, May 17-18, August 16-17, November 22-23, 1996.

Director of "Quest for Excellence in Continence Care" November 19-21 1998

8. Previous Administrative and/or Clinical Appointments:

9. Licensures/Boards:
General Medical Council Registration No. - 1339990
Educational Commission for Foreign Medical Graduates No.-272-0621

10. Specialty Boards:
Higher Specialist Training in Urology (Great Britain):
Enrollment for higher training - October 1982
Full Accreditation in Urology - October 1986

11. Education:

1968 – 1974 University of Aberdeen Medical School
Distinctions and Awards
Medical Biology Class Prize
Certificate of Merit in Medicine
Certificate of Merit in Pharmacology
John Hunter Bursary Award 1974
Final year student Award for Surgical Studies

12. Postgraduate Training:
Post Graduate Examinations and Qualifications
June 1974 M.B., Ch.B. (Aberdeen)
June 1976 Primary FRCS
July 1976 E.C.F.M.G.
May 1979 Final FRCS (England)
June 1979 Final FRCS (Edinburgh)
January 1988 Foreign Medical Graduates Examination
in Medical Sciences
June 1988 Federal License Examination
13. Military or Government Service:
14. Committee Memberships:
 - a. National and International:
Medical and Scientific Societies:
Member of British Medical Association - 1974
Member of Scottish Medical & Dental Defense - 1974
Fellow of the Royal College of Surgeons of England - 1979
Fellow of the Royal College of Surgeons of Edinburgh - 1979
Member of the International Continence Society - 1982
Member of British Assoc. of Urological Surgeons-1985
Member of the Urodynamic Society - 1988
American Medical Association - 1989
Member, Project Advisory Committee, National Association for Continence – 2004-2008
Board of Directors, National Association for Continence – 2006-Present
Chairman of Board of Directors, National Association for Continence – 2009-Present
Member, Editorial Board, European Association of Urology - 2011
 - b. Regional and State:
Georgia Urologic Association - 1990
Atlanta Urological Association - 1990 * elected official
American Urogynecology Society - 1992
Southeastern Section AUA - 1993 * elected official
American Urological Association - 1994
National Urological Forum, elected by invitation - 1994
Society for Basic Urologic Research – 1994
Credentials Committee, Emory University Hospital and Emory Healthcare – 2006-present
Medical Executive Committee, Emory University Hospital and Emory Healthcare – 2006-present
Georgia Urological Association, Medical Executive Committee – 2007-2008
15. Editorships and Editorial Boards:
 1. Prostatic Disorders. Editor David F Paulson
Urodynamic Evaluation of Benign and Malignant Disease of the Prostate.
Chapter 3 Ps 51-67. Lea & Febiger Philadelphia 1989
 2. Galloway, Niall T.M. Classification and Diagnosis of Neurogenic Bladder
Dysfunction. In: Problems in Urology- Neurourology.
Guest eds, George D. Webster and Niall T.M. Galloway,.
Philadelphia: JB Lippincott, 1989:3(1) pp.1

3. Galloway, Niall T.M. Management of Neurogenic Bladder in Spinal Cord Injury: Achieving a Catheter-Free Status. In: Problems in Urology. Neurourology. David F. Paulson, ed., George D. Webster and Niall T.M. Galloway, Guest eds. Philadelphia: JB Lippincott, 1989:3(1) pp. 40
4. Galloway, Niall T. M. Occult Neuropathic Vesicourethral Problems. In: Problems in Urology. Neurourology. David F. Paulson, ed., George D. Webster and Niall T.M. Galloway, Guest eds. Philadelphia: JB Lippincott, 1989:3(1) pp. 159
5. Galloway, Niall T. M. Pain with External Sphincter Dysfunction. In: Problems in Urology. Pain of Genitourinary Origin. David F. Paulson, ed., Emil A. Tanagho, Guest ed. Philadelphia: JB Lippincott, 1989:3(2) pp 346
6. Galloway, NTM, Blaivas, J. Electromyography in Lower Urinary Tract Dysfunction. In: Diagnostic Techniques in Urology. Chapter 22. PH O'Rielly, NJR George, Weiss, RM eds., Philadelphia: WB Saunders, 1990:335-352
7. Galloway, Niall T.M. Urinary incontinence. In: Medicine for the Practicing Physician, 3rd Ed., Section 19, Chapter 3. J.W. Hurst, ed. Boston: Butterworth-Heinemann, 1992:1327
8. Irwin, Paul P., Galloway, Niall T.M. Pneumaturia and fecaluria. In: Medicine for the Practicing Physician, 3rd Ed., Section 19, Chapter 9. J. W. Hurst, ed. Boston: Butterworth-Heinemann, 1992: 1333
9. Galloway, Niall T.M., Irwin, Paul P. Urethral stricture. In: Medicine for the Practicing Physician, 3rd Ed., Section 19, Chapter 12. J. W. Hurst, ed. Boston: Butterworth-Heinemann, 1992:1337
10. Irwin, Paul P. and Galloway, Niall T.M. Surgical Management of Interstitial Cystitis. In: The Urologic Clinics of North America. Philip M. Hanno, Guest ed. Philadelphia: WB Saunders Co., 1994:21(1)145
11. Galloway, Niall T.M. Transurethral Resection of the Prostate. In: Medical Management of the Surgical Patient, 3rd Ed., Michael F. Lubin, H. Kenneth Walker, Robert B. Smith III, eds. Philadelphia: JB Lippincott, 1995:627
12. Galloway, Niall T.M. Management of Urological Problems in Neurosurgery. In: The Practice of Neurosurgery. George Tindall, Paul Cooper, Daniel Barrow, eds. Baltimore: Williams & Wilkins, 1995:317-329
13. Niall T.M. Galloway, R.E.S. El-Galley. Urinary Retention. In: JW Hurst, ed. Medicine for the Practicing Physician, 4th ed. Norwalk, CT: Appleton and Lange, 1996:1451

14. R.E.S. El-Galley, Niall T.M. Galloway. Urinary Incontinence.
In: JW Hurst, ed. Medicine for the Practicing Physician, 4th ed.,
Norwalk, CT: Appleton and Lange, 1996:1452-1454
15. R.E.S. El-Galley, Niall T.M. Galloway. Pneumaturia and Fecaluria.
In: JW Hurst, ed. Medicine for the Practicing Physician, 4th ed.,
Norwalk, CT: Appleton and Lange, 1996:1458-1459
16. R.E.S. El-Galley, Niall T.M. Galloway. Urethral Stricture.
In: JW Hurst, ed. Medicine for the Practicing Physician, 4th ed.,
Norwalk, CT: Appleton and Lange, 1996:1463-1465
17. R.E.S. El-Galley, Niall T.M. Galloway. Orchitis.
In: JW Hurst, ed. Medicine for the Practicing Physician, 4th ed.,
Norwalk, CT: Appleton and Lange, 1996:1479-1481
18. R. G. Bruce, N. T. M. Galloway: Diagnostic and therapeutic considerations in catheter
associated bacteriuria in the hospital/chronic care facility. Antibiotics for Clinicians 1999
17. Manuscript reviewer:
18. Honors and Awards:
Special Awards:
John Hunter Award for Surgical Studies, Univ. of Aberdeen-1974
British Association of Urological Surgeons - Bard Medal-1985
Research Essay First Prize - "The Occult Neuropathic Bladder",
Presented in Eastbourne, England - June 1985
Welsh Urological Society Travelling Fellowship - 1986
Teacher of the Year - Presented by Chief Residents
Emory University Hospital - June, 1990
President of National Urology Forum 1999
Member of Scientific Committee for ICS annual meeting 1999
SLC Industries, Inc. – 2007; selected as one of “America’s Top Urologists”.
Official Award Acceptance – Emory University (Uromedica) – 2005 - 2008:
“Act for Treatment of Female Stress Urinary Incontinence”; human subjects.

Best video AUGS 2013

Nominated by Southeast section for annual AUA Victor Politano award 2014

19. Society Memberships:

Kansas City Gynecologic Society 11/17/2005
20. Patents

United States Patent:
No. 4,738,667 granted for pre-formed catheter assembly - 1988 Issued: 1988

International PCT Patent Application for
TARGETING THERAPEUTIC AGENTS
Serial No.: PCT/US2010/044224 Filing Date: August 3, 2010
Emory File No.: 08043 Facet File No.: 2G02.2-630 Our File No.: 2E11.2-010

Japanese National Phase Patent Application for

TARGETING THERAPEUTIC AGENTS

Based on PCT/US10/44224

Our File No.: 2E11.2-010 JP

TARGETING THERAPEUTIC AGENTS filed on August 3, 2010 and assigned Serial Number PCT/US2010/044224, which claims priority to U.S. Serial Number 61/230,905 filed August 3, 2009

Targeting Therapeutic Agents Patent will be validated in the United Kingdom, France and Germany

Targeting Therapeutic Agents Ref: 08043 US United States Patent granted June 2015

16. Grant Support:
National Cancer Institute Grant:
Co-investigator in CCOP Grant Proposal awarded by NCI for the
study of cancer therapy and cancer control strategies in black
Americans. Principal investigator - Melvin R. Moore, M.D.

MED Institute, Inc., MyoSite Stress Urinary Incontinence US Clinical Study - A Double-blind, Randomized, Controlled Trial Comparing the Safety and Efficacy of AMDC-USR (cultured human muscle cell preparation with Placebo in Female Subjects with Stress Urinary Incontinence - in negotiation

17. Formal Teaching:

Dr Galloway is a native of Scotland; he graduated from the Aberdeen University school of medicine in 1974, and went on to Edinburgh for internship. He taught Anatomy at the University of Edinburgh, before going to Bath in England for residency training in Surgery. He was awarded Fellowship of the Royal College of Surgeons of England in 1979, and later Fellowship of the Royal College of Surgeons of Edinburgh. He returned to Edinburgh for a further two years of post Fellowship training in General Surgery, before being appointed Lecturer in Urology at the University of Edinburgh. His major research interests were in the areas of renal transplantation, neurourology and lower urinary tract dysfunction. At that time, he was able to initiate collaboration between Urology and Gynecology, which led to the creation of the first multidiscipline Continence Clinic in Scotland.

In 1986, Dr Galloway was awarded the annual medal of the British Association of Urological Surgeons for the development of novel diagnostic methods in the diagnosis of Neurogenic Bladder Dysfunction. He was appointed Senior Registrar at the University Hospital of Wales in Cardiff, where he had responsibilities for the National Spinal Injury Center in addition to the University Hospital of Wales and Cardiff Royal Infirmary. Dr Galloway was invited to Duke University as a Research Fellow and later was appointed to the faculty as visiting professor.

He was invited to join the faculty of Emory University School of Medicine in Atlanta, in 1989. The early responsibilities included Chief of Urology at Grady Memorial Hospital, a position that he held until 1995. In 1992, he founded the Continence Center of Emory University, which has grown to become a major regional referral center for patients with complex continence problems. The Continence Center is staffed by Urology, Gynecology and GI physicians as well as specialty trained continence nurses. The center provides all aspects of comprehensive assessment and treatments for pelvic floor dysfunction including incontinence, prolapse, bowel problems and pelvic pain.

The center provides clinical training for the nurses of the Wound/Ostomy/Continence program of the Emory School of Nursing. Dr Galloway is the program director of a three-day postgraduate course - "Quest for Excellence in Continence Care". The course is offered every quarter for physicians and nurses from all over the US and includes all aspects of evaluation and conservative managements. A special focus of the meeting is pelvic floor anatomy, recognition of support defects and surgical strategies for pelvic floor reconstruction.

Special Study Courses Attended:

Management of spinal injuries - Sheffield, 1979
 Electromyography/Neurophysiology Seminar - Bristol, 1983
 Endourology Teaching Course - The London Hosp. - London, 1985
 Controversies in Urology - Institute of Urology - London, 1985
 Endourology Teaching Course - Amsterdam, Netherlands - 1985
 American Urological Association - New York, New York - 1986
 International Continence Society Meeting - Boston, Mass.- 1986
 Southeastern Section of AUA, New Orleans - 1987
 American Urological Association, Anaheim, CA - 1987
 International Single Fibre EMG Course, North Carolina -1987

18. Lectureships, Seminar Invitations, and Visiting Professorships:

Address To Learned Societies:

Royal Society of Medicine (Urology) - London, 1979
 South West of England Surgeon's Annual Meeting - Bath, 1981
 Royal Medical Society of Edinburgh - Edinburgh, 1982
 International Continence Society - Leiden, 1983
 Southern Surgeons (of America) - Edinburgh, 1983
 British Association of Urological Surgeons - Harrogate, 1983
 The Scottish Urological Association - Edinburgh, 1983
 British Association of Urological Surgeons - Dublin, 1984
 Edinburgh Urological Festival - Edinburgh, 1984
 South West Urological Society - Plymouth, 1985
 Welsh Urological Society - Newport, 1985
 British Association of Urological Surgeons - Eastbourne, 1985
 * International Congress of Spinal Cord Injury -Oslo, Norway, 1986
 * British Association of Urological Surgeons
 & Canadian Urological Association - London, 1986
 Duke Urological Assembly - Pinehurst, North Carolina, 1986
 Society of Urologists in Charlotte - Charlotte, NC, 1987
 Southeastern Section of Amer. Urol. Assoc. - New Orleans, 1987
 American Urological Association - Anaheim, California, 1987
 British Association of Urological Surgeons - Edinburgh, 1987
 Piedmont Society of OB/GYN Winter Symposium - Univ. of
 North Carolina, Chapel Hill - Bowman Gray, NC, 1988
 Pediatric Symposium, Duke University - Durham, NC, 1988
 American Urological Association - Boston, Mass., 1988
 British Assoc. of Urological Surgeons-Buxton, England, 1988
 Southeastern Section of Amer. Urol. Assoc.-Boca Raton, Fla. 1988
 Texas Assoc. of Genitourinary Surgeons - Durham, NC, 1988
 Duke Urologic Assembly - Bermuda, 1988
 Southeastern Section of Amer. Urol. Assoc.-Hilton Head, SC, 1989
 American Urological Association - Dallas, Texas 1989
 Interstitial Cystitis Assoc./National Institutes of Health
 Research Meeting, New Orleans, LA. - 1990
 Interactive Obstructive Uropathy, University of Manchester,
 Manchester, England - April, 1990
 American Urological Association - New Orleans, LA. - 1990
 Masters in Gynecology - July, 1990 Edinburgh
 Emory University and Edinburgh University Edinburgh Scotland
 American Urological Association - Toronto, 1991.
 American Urogynecology Society - Newport Bch. California 1992
 Southeast Section, AUA - April 13, 1996.
 "Co-Moderator, Session of Incontinence/Neurology"
 Southeast Section, AUA - April 13, 1996.
 "Moderator, Panel Discussion, Computers in Urology"
 Speaker, Spina Bifida Association of Georgia, Bowel & Bladder Workshop – March 2008

Advances in Urology Dec 7 2013, Post Prostatectomy Incontinence work up and treatment

SESAUA presentation Patient asymmetry – a predictor of success in sacral neuromodulation
 March 21, 2013

19. Invitations to National or International Conferences

Invited Presentations

Florida Association of Enterostomal Therapists May 29th May 98
Annual Meeting The Biology of Incontinence Clearwater Beach Florida

International Meeting Emory Urologic Oncology
Magnetic Stimulation for the Treatment of Incontinence May 98

Clinical Information for Coders in Urology Georgia Health Information Management Association
June 1998 Cobb Galleria Atlanta

Dutch Urological Association Annual Meeting Groningen September 1999

EMORY CME / GHA TELNET program The Biology of Continence and the Treatment of Urinary
Incontinence
Distance Learning Project March 98
Surgical Grand Rounds April 5, 2007- "Surgical Symmetry"

Conference of the Georgia & S. Carolina Urological Associations Annual Meeting 2007

Speaker/Session Chairman, "Patterns of Sacral Neurogenic Deficits in Man – Clinical and
Therapeutic Importance." First Annual World Congress of NeuroTalk. Singapore, June 26, 2010.

Pathway to Prevention of lower urinary tract symptoms in women. NIH/ NIDDK symposium
Washington DC invited speaker Feb 14 2014

20. Other Activities:

Special Study Courses Attended:

Management of spinal injuries - Sheffield, 1979
Electromyography/Neurophysiology Seminar - Bristol, 1983
Endourology Teaching Course - The London Hosp. - London, 1985
Controversies in Urology - Institute of Urology - London, 1985
Endourology Teaching Course - Amsterdam, Netherlands - 1985
American Urological Association - New York, New York - 1986
International Continence Society Meeting - Boston, Mass.- 1986
Southeastern Section of AUA, New Orleans - 1987
American Urological Association, Anaheim, CA - 1987
International Single Fibre EMG Course, North Carolina -1987

21. Bibliography:

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16. Galloway NTM, Gabale D, Irwin PP: Interstitial Cystitis or Reflex Sympathetic Dystrophy of the Bladder? *Seminars in Urology* 9(2):148-153, 1991
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28. Grady Bruce, Rizk E.S. El-Galley, Judy Wells, Niall T. Galloway: Antegrade Continence Enema (ACE) For The Treatment Of Fecal Incontinence In Adults: Use of Gastric Tube for catheterization access to the descending colon. *J. Urol.* 161:1813-1816, 1999
29. Grady Bruce, Rizk E.S. El-Galley, Mohamed Saleem, and Niall Galloway: Paravaginal Defect Repair In The Treatment Of Female Stress Urinary Incontinence And Cystocele. *Urology* 54:647-651, 1999.

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34. Healy KA, Baumgarten DA, Lendvay TS, Fountain AJ, Galloway NT, Ogan K. Occult spinal dysraphism and urolithiasis: are patients at higher risk of stone disease? J Endourology. 2007 Nov;21(11):1293-6.
35. Aboseif SR, Franke EI, Nash SD, Slutsky JN, Baum NH, Tu le M, Galloway NT, Pommerville PJ, Sutherland SE, Bressette JF. The Adjustable Continence Therapy (ACT) System for Recurrent Female Stress Urinary Incontinence: 1-Year Results of the North America Clinical Study Group. J Urol. May;181(5):2187-91. Epub 2009 Mar 17.
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38. Five Years Follow-Up of Adjustable Continence Therapy (ACT) in the Treatment of Recurrent Female SUI
Niall T. Galloway, Sherif R. Aboseif, Pejvak Sassani, Ethan I. Franke, Steven D. Nash, Joel N. Slutsky, Mai Le Tu, Peter J. Pommerville, Neil H. Baum, Suzette E. Sutherland
Abstract | References Full-Text PDF Full-Text HTML,, ePub, PP. 132-137, Pub. Date: May 22, 2013 DOI: 10.4236/oju.2013.32025 Downloads: 88 Google Scholar Open Access Library
39. Management of Bleeding Associated Severe Gastritis of the Gastric Mucosa in a Patient with a Gastrocystoplasty. Journal of Clinical Gastroenterology 13394R1, 2013

22. Book chapters:

1. Prostatic Disorders. Editor David F Paulson
Urodynamic Evaluation of Benign and Malignant Disease of the Prostate.
Chapter 3 Ps 51-67. Lea & Febiger Philadelphia 1989
2. Galloway, Niall T.M. Classification and Diagnosis of Neurogenic Bladder Dysfunction. In: Problems in Urology- Neurourology.
Guest eds, George D. Webster and Niall T.M. Galloway,,
Philadelphia: JB Lippincott, 1989:3(1) pp.1
3. Galloway, Niall T.M. Management of Neurogenic Bladder in Spinal Cord Injury: Achieving a Catheter-Free Status. In:
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4. Galloway, Niall T. M. Occult Neuropathic Vesicourethral Problems.
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George D. Webster and Niall T.M. Galloway, Guest eds.
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J. W. Hurst, ed. Boston: Butterworth-Heinemann, 1992: 1333
9. Galloway, Niall T.M., Irwin, Paul P. Urethral stricture.
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J. W. Hurst, ed. Boston: Butterworth-Heinemann, 1992:1337
10. Irwin, Paul P. and Galloway, Niall T.M. Surgical Management of Interstitial Cystitis.
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Philip M. Hanno, Guest ed. Philadelphia: WB Saunders Co., 1994:21(1)145
11. Galloway, Niall T.M. Transurethral Resection of the Prostate.
In: Medical Management of the Surgical Patient, 3rd Ed.,
Michael F. Lubin, H. Kenneth Walker, Robert B. Smith III, eds.
Philadelphia: JB Lippincott, 1995:627
12. Galloway, Niall T.M. Management of Urological Problems in Neurosurgery.
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Norwalk, CT: Appleton and Lange, 1996:1451
14. R.E.S. El-Galley, Niall T.M. Galloway. Urinary Incontinence.
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15. R.E.S. El-Galley, Niall T.M. Galloway. Pneumaturia and Fecaluria.
In: JW Hurst, ed. Medicine for the Practicing Physician, 4th ed.,
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16. R.E.S. El-Galley, Niall T.M. Galloway. Urethral Stricture.
In: JW Hurst, ed. Medicine for the Practicing Physician, 4th ed.,
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17. R.E.S. El-Galley, Niall T.M. Galloway. Orchitis.
In: JW Hurst, ed. Medicine for the Practicing Physician, 4th ed.,
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18. R. G. Bruce, N. T. M. Galloway: Diagnostic and therapeutic considerations in catheter associated bacteriuria in the hospital/chronic care facility. Antibiotics for Clinicians 1999

23. ABSTRACTS

1. 1987 SESAUA 51st Annual Meeting
Electromyography of Urethral Sphincter in Young Men with Urinary Retention
Niall T M Galloway, John E Danneberger and George D Webster
1. 1987 SESAUA 51st Annual Meeting
Lower Urinary Tract Reconstruction by Combined Enterocystoplasty and
Artificial urinary Sphincter Implantation
George D Webster, Michael I Maggio and Niall T M Galloway
3. 1987 SESAUA 51st Annual Meeting
Salvage Urethroplasty after Failed Repairs of Pelvic Fracture Membranous
Urethral Strictures George D Webster, Kendall L Wise and Niall T M Galloway
4. 1988 SESAUA 52nd Annual Meeting
Neonatal Urodynamics in Myelodysplasia
William W Bonney, Niall T M Galloway and George Webster
5. 1988 SESAUA 52nd Annual Meeting
Diabetic Uropathy - A Rare Urodynamic Finding
William W Bonney, Niall T M Galloway and George D Webster

6. 1988 SESAUA 52nd Annual Meeting
The Bladder Chart - An Aid to Urodynamic Diagnosis
John E Danneberger, Niall T M Galloway and George D Webster
7. 1988 SESAUA 52nd Annual Meeting
Lateralisation of Urethral Dysfunction Using Computer Analysis of
Electromyography. Niall T M Galloway, Sanjeev D Nandedkar and George D
Webster
8. 1988 SESAUA 52nd Annual Meeting
Clam Augmentation Enterocystoplasty for Detrusor Hyperactivity
George D Webster, Niall T M Galloway, William W Bonney and Michael I Maggio
9. 1988 SESAUA 52nd Annual Meeting
Voiding Difficulty After Urethral Suspension
George D Webster, Niall T M Galloway, Nancy A Little and William W Bonney
10. 1989 British Association of Urologic Surgeons
A Score to Predict Upper Tract Deterioration in Myelodysplasia
Niall T M Galloway, John A Mekras and George D Webster
11. 1989 SESAUA 53rd Annual Meeting
Urodynamic Findings and Results of Needle Suspension Cystourethroplasty
in Patients with Combined Stress and Urge Incontinence.
Anurag K Das, George D Webster, John A Mekras and Niall T M Galloway
12. 1989 SESAUA 53rd Annual Meeting
New Animal Model To Investigate Urethral Sphincter Innervation
John A Mekras, Niall T M Galloway and George D Webster
13. 1989 SESAUA 53rd Annual Meeting
An Integrated Computer System for Clinical and Urodynamic Data Management
Niall T M Galloway and George D Webster
14. 1989 SESAUA 53rd Annual Meeting
A Score to Predict Upper Tract Deterioration in Myelodysplasia
Niall T M Galloway, John A Mekras and George D Webster
15. 1989 AUA 84th Annual Meeting
The Bladder Chart: A Cost Effective Adjunct in the Evaluation of Voiding
Dysfunction
John E Danneberger, Niall T M Galloway and George D Webster
16. 1989 AUA 84th Annual Meeting
A Score to Predict Upper Tract Deterioration in Myelodysplasia
Niall T M Galloway, John A Mekras and George D Webster
17. 1989 AUA 84th Annual Meeting
An Integrated Computer System for Clinical and Urodynamic Data Management
Niall T M Galloway and George D Webster
18. 1989 AUA 84th Annual Meeting
New Animal Model to Investigate Urethral Sphincter Innervation
John A Mekras, Niall T M Galloway and George D Webster
19. 1989 AUA 84th Annual Meeting
Spinal Cord Infarction and Neurogenic Bladder
William W Bonney, Niall T M Galloway and George D Webster
20. 1990 SESAUA 54th Annual Meeting
Urologic Cancers in Patients with Aids
Martin D Bastuba, Niall T M Galloway, J M White, and Sam D Graham
21. 1991 SESAUA 55th Annual Meeting
A Better Catheter For The Nineties
Niall T M Galloway, Ronald Chee-Awai and Paul P Irwin
22. 1991 SESAUA 55th Annual Meeting
An Alternative Hypothesis for the Pathogenesis of Interstitial Cystitis
Niall T M Galloway and Paul P Irwin

23. 1991 AUA 86th Annual Meeting
What Determines the State of the Upper Tracts in Prune Belly Syndrome
Niall T M Galloway, John R Woodard, Thomas S Parrott, James J Woolpert,
Bruce H Broecker and Rafael Gosalbez
24. 1991 AUA 86th Annual Meeting
An Alternative Hypothesis for the Pathogenesis of Interstitial Cystitis
Niall T M Galloway, Deven R Gabale and Paul P Irwin
25. 1991 AUA 86th Annual Meeting
A Better Catheter for the Nineties
Niall T M Galloway, Ronald Chee-Awai and Paul P Irwin
26. 1991 AUA Postgraduate Seminar New Orleans
Lower Urinary Tract Problems in Female Patients including Urinary
Tract Infections and Incontinence
27. 1992 International Continence Society, Halifax
Ambulatory Urodynamics: A Useful Technique to Retain the Microtip Pressure
Catheter
Niall T M Galloway
28. 1992 International Continence Society, Halifax
Abnormal Thermoregulation in Interstitial Cystitis
- further evidence for the role of the sympathetic nervous system.
Paul Irwin and Niall T M Galloway
29. 1992 International Continence Society, Halifax
Epidural Blockade for Pain Relief in Interstitial Cystitis
Paul Irwin and Niall T M Galloway
30. 1992 Emory Urology Forum in Bermuda
Complex Lower Urinary Reconstruction
Long-term Considerations after Reconstruction
Neurourology - Buzzword or Useful Clinical Tool? Niall T M Galloway
31. 1992 AUA 87th Annual Meeting
Sympathetic Blockade in the Management of Interstitial Cystitis
Paul Irwin, William D Hammonds and Niall T M Galloway
32. 1993 Edinburgh Urological Festival Joint Meeting with the Emory Urology Forum
Non-Neurogenic Neurogenic Nonsense
Niall T M Galloway
33. 1993 SESAUA 57th Annual Meeting
Early Results of Gastrocystoplasty in Adults
Ajay Singla, Rafael Gosalbez and Niall T M Galloway
34. 1993 SESAUA 57th Annual Meeting
A Critical Review of Precertification Criteria for TURP
Niall T M Galloway and Ajay Singla
35. 1993 SESAUA 57th Annual Meeting
Unfavourable Outcome after TURP
Ajay Singla and Niall T M Galloway
36. 1993 NIH ICA Research Meeting Florida
Evidence of Neurogenic Deficit in IC
Niall T M Galloway
37. 1993 NIH ICA Research Meeting Florida
On the Mechanisms of Urinary Frequency and Urgency
Niall T M Galloway
38. 1993 British Association of Urological Surgeons Annual Meeting
Is Clinical Evaluation Adequate to Select Patients for TURP?
Niall T M Galloway and Ajay K Singla
39. 1993 British Association of Urological Surgeons Annual Meeting
Abnormal Pedal Thermoregulation in Interstitial Cystitis
Paul P Irwin and Niall T M Galloway

40. 1993 Third Annual Emory Urologic Alumnus Meeting
Painful Bladder Syndromes in Women
Niall T M Galloway
41. 1994 National Institute of Health, Bethesda
Women's Urological Health Research
A Pattern of Neurogenic Deficit in Adults
Niall T M Galloway, Frances M Dyro and Rizk El-Galley
42. 1994 National Institute of Health, Bethesda
Women's Urological Health Research
Are there Unrecognised Causes for Lower Urinary Tract Symptoms in Adults
Rizk El-Galley, Frances M Dyro and Niall T M Galloway
43. 1994 National Institute of Health, Bethesda
Women's Urological Health Research
Clinical Evidence of a Neurogenic Deficit in Interstitial Cystitis
Niall T M Galloway, Rizk El-Galley and Frances M Dyro
44. 1994 National Institute of Health, Bethesda
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On the Mechanisms of Urinary Frequency and Urgency
Niall T M Galloway, Rizk El-Galley and Frances M Dyro
45. 1994 AUA 89th Annual Meeting
Priapism: review of 55 patients treated over the last eight years at Emory University
Todd H Hoekstra, Michael A Witt and Niall T M Galloway
46. 1995 SESAUA Annual Meeting
Hypospadias: Difficult Surgery or Incompetent Tissues - EGF and EGFR in Hypospadias
Rizk El-Galley, Patricia B. DeRose, Edwin a. Smith, Cynthia Cohen, John A. Petros, John R. Woodard, Niall T. M. Galloway.
47. 1995 SESAUA Annual Meeting
Normal Range PSA VS Age Specific PSA in Screening Prostatic Adenocarcinoma.
Rizk El-Galley, John A. Petros, William H. Sanders, Thomas E. Keane, Niall T. M. Galloway, William H. Cooner, Sam D. Graham.
48. 1995 SESAUA Annual Meeting
Nerve Fiber Density in Hypospadias
RES El-Galley, P.B. DeRose, E Smith, C Cohen, JA Petros, J Woodard and N.T.M. Galloway
49. 1995 AUA 90th Annual Meeting
Female Urology - Surgery, periurethral injection II.
Moderators: Niall T.M. Galloway and Norman R. Zinner.
50. 1996 AUA 91st Annual Meeting
Rectus muscle sling procedure for the treatment of type III stress urinary Incontinence.
M.F. Townsend III, J. Warshaw, R. El-Galley, N.T.M. Galloway
51. 1996 AUA 91st Annual Meeting Plenary Session III.
Highlights. Urodynamics and Incontinence. Niall T.M. Galloway.
52. 1997 SESAUA
Importance of Urodynamic Evaluation of Urinary Obstruction in Men
El-Galley R.E.S. Saleem M., Galloway N.T.M.
53. 1997 SESAUA
Artificial Urinary Sphincter for Severe Urinary Incontinence
Saleem M., El-Galley R.E.S., Aboel-Nasr M, Galloway N.T.M.
54. 1997 AUA 92nd Annual Meeting
Outcomes of urethroplasty for severe urethral stricture.

- Niall T.M. Galloway, Mamdouh Aboel-Nasr, Mohamad D. Saleem and R.E.S. El-Galley. J. Urol. 157(4): 396 Abstract 1553, April 1997.
55. 1997 AUA 92nd Annual Meeting
Importance of urodynamic evaluation of urinary obstruction in men.
Rizk El-Galley, Mohamad Saleem and Niall Galloway.
J. Urol. 157(4):439, Abstract 1716, April 1997.
56. 1998 SESUA
Continent Urinary Diversion Using a Gastric Segment
Rizk ES El-Galley, Mamdouh Abuelnasr, Dyaa M. Saleem,
Tarek El-Leithy, and Niall TM Galloway
57. 1998 SESUA
Paravaginal Defect Repairs in the Treatment of Stress Urinary Incontinence
Rizk ES El-Galley, Mohamad Saleem, Mamdouh AboelNasr, Tarek El-Leithy
and Niall T.M. Galloway.
58. 1999 SESAUA
The influence of Hysterectomy on lower urinary tract problems in patients
attending a continence center. Hysterectomy - An Important Cause Of Lower
Urinary Tract Dysfunction. abstract 27
R.E.S. El-Galley, G.R. Bruce, and N.T.M. Galloway.
59. 1999 SESAUA
Extracorporeal Magnetic Innervation (Exmi) Therapy For Stress Urinary
Incontinence N.T.M. Galloway, R.E.S. EL-Galley, H. Russell, S.J. Carlan, R.
Appell, and P.K Sand
60. 1999 SESAUA
Bladder And Rectal Control After Radical Perineal Prostatectomy
R. E.S. El-Galley, T. R. El-Leithy, T.E. Keane, N.T.M. Galloway, and Sam D.
Graham, Jr.
61. 1999 SESAUA
Analysis Of Lower Urinary Tract Symptoms After Radical Prostatectomy
R.E.S. El-Galley, R. Talic, T.E. Keane, H.S. Clarke, J.A. Petros, and N.T.M.
Galloway.
62. 1999 SESAUA
Antegrade Continence Enema (ACE) For The Treatment Of Fecal Incontinence
In Adults: Use Of Gastric Tube For Catheterizable Access To The Descending
Colon. Abstract 32
Grady Bruce, Rizk ES El Galley, Niall TM Galloway.
63. 1999 SESAUA
Urodynamic Correlates In Women Undergoing Paravaginal Defect Repair For
Stress Urinary Incontinence And Cystocele; abstract 18 March 1999.
Grady Bruce, Rizk ES El Galley, Niall TM Galloway.
64. 1999 Society for Urodynamics & Female Urology May 1, Dallas
Surgery for Interstitial Cystitis Niall TM Galloway
65. 1999 AUA
Extracorporeal Magnetic Innervation (ExMI) Therapy For Stress Urinary
Incontinence
N.T.M. Galloway, R.E.S. EL-Galley, H. Russell, S.J. Carlan, R. Appell, and P.K
Sand
66. 1999 SCS - AUA
Use of the Rectus Abdominis flap in the treatment of complex and refractory
female urethrovaginal fistula. SCS-AUA, 78th annual meeting, September 1999
Bruce R G, El-Galley RES and Galloway NTM
67. 1999 SCS – AUA
Paravaginal Defect Repair: The anatomic approach to cystourethrocele and
female pelvic reconstruction. 78th Annual Meeting, September 1999
Bruce R G, Maculuso J N, El-Galley RES and Galloway NTM

68. 1999 American Urogynecology Society (AUGS)
Post-Anal Levatorplasty: A useful adjunct in female pelvic floor reconstruction.
P.10 Oct 99
Bruce R G, El-Galley RES and Galloway NTM
69. 1991 International Bladder Symposium
Factors influencing success with Extracorporeal Magnetic Innervation (ExMI)
treatment of mixed urinary incontinence. Abstract. International Bladder
Symposium, Washington, DC, November 1999. Sand PK, Appell RA, Bavendam
TG, Whitmore K, Carlan SJ and Galloway NTM.
70. 2000 SESAUA papers X4
71. 2000 American Geriatrics Society /American Federation for Aging Research
May 19 - Trader's of the Lost Art: Senior Expert Clinicians Tell All.
How to Conduct the Physical Examination of the Incontinent Patient Invited
Speaker
72. 2008 SUFU
The Adjustable Continence Therapy (ACT) System: Preliminary Results of the
North America ACT Clinical Study Group. Abstract SUFU Meeting, Miami, 2008.
Aboseif S, Galloway N, et. al.
73. 2010 ICS
Good Initial ACT® Balloon Placement, Requiring Fewer Adjustments, Reduces
Likelihood of Later complications. Abstract 747. International Continence Society
2010. Galloway N, Aboseif S, Nash S, et al.
74. 2010 ICS
Pre-Operative Predictors of Success and of Complications with ACT®
Implantation for Stress Urinary Incontinence. Abstract 776. International
Continence Society 2010. Aboseif S, Slutsky J, Galloway N, et al.
75. 2010 AUA
Medium Term Results of the Adjustable Continence Therapy (ACT) in the
Treatment of Recurrent Stress Urinary Incontinence. Abstract 1504. American
Urological Association Annual Meeting 2010. Sutherland S, Nash S, Slutsky J,
Galloway N, et al.
76. 2011 AUA
Adjustable Continence Therapy for Recurrent Stress Urinary Incontinence: Five
Year Follow Up. American Urological Association Annual Meeting, Washington,
DC 2011. Galloway NTM, Aboseif, SR, Baum NH, Tu LM, Bresette JF,
Pommerville PJ, Sutherland SE, Slutsky JN and Nash SD.
77. 2011 AUA
The Neurological Examination of the Urological Patient. Post Graduate Course.
American Urological Association Annual Meeting, Washington, DC 2011.
Galloway N, Hood N.
78. 2011 ICS
Physical Signs of Asymmetry: A Guide to Successful Interstim Therapy. Abstract
742, ICS 41st Meeting, Glasgow, September 2011. Figler BD, Jafri SMA,
Galloway N.
79. 2011 ICS
Abstract 748. ICS 41st Meeting, Glasgow, September 2011. Jafri SMA,
Butterworth J, Galloway N.

Niall Galloway CV – updates 2017

Mentorship

Supervisor and Mentor of Candidate Ng, Gladys Y Emory University Department of Urology, One Year Fellowship in Reconstructive Urological Surgery. Graduated June 2015

Supervisor and Mentor of Candidate Espy, Paul G Emory University Department of Urology, One Year Fellowship in Reconstructive Urological Surgery. Graduated June 2016

Thesis Director and Mentor for Dissertation by Kathy E. Davis entitled - Clinical Outcomes Involving the Use of Extracorporeal Magnetic Innervation in the Treatment of Urinary Incontinence. Dr. Davis was awarded her Doctorate in Nursing Sciences by Georgia State University, Atlanta Georgia - June 2015

Under Graduate Presentation

Annual Anatomy Lecture Course for M-1 Medical Student Class April 2015

Post-Graduate Presentations

Advances in Urology: Annual Regional Meeting for Urologists presented by Emory University School of Medicine, Department of Urology December 5 2014

Management of Mesh Nightmares - Niall Galloway

Complications following urinary diversion- Niall Galloway and Gladys Ng

International Presentations

Biotensegrity Interest Group – Key note speaker Biotensegrity Model of Pelvic Support Anatomy, British Fascia Society Annual Meeting, Pre conference Seminar, Worcester, England June 28, 2016

On Human Growth and Form – Invited Speaker Annual Human Anatomy Meeting, University of Dundee Scotland July 2-4, 2016

Leadership

Director of the Center for Spina Bifida Research and Prevention, Rollin's School of Public Health, Emory University – Director of Transitional Care from Adolescence to Adult

Research

Co- PI A Double-blind, Randomized, Controlled Trial Comparing the Safety and Efficacy of Autologous Derived Muscle Cell – USR with Placebo in Female Patients with Stress Urinary Incontinence, Emory University School of Medicine

Protocol # 13-003 Sponsor Cook MyoSite, Incorporated. Emory IRB File Number W00000422

Abstracts

European Association of Urology, March 2015 Annual Meeting in Madrid, Spain

Published Abstract Reference MAD15-6616 Clinical examination findings of Asymmetry: A Guide to Successful Interstim Therapy

National Awards

Galloway nominated by Southeast Section as candidate for annual American Urological Association Award for 2014 in recognition and memory of Professor Victor Politano

US Patent

Granted Patent for Novel Hand Assisted Video Surgical Device for Targeting Therapeutic Agents – Specifically Peri-Urethral Delivery of Bulking Agents for the Treatment of Stress Urinary Incontinence

Ref: 08043 US: Letters of Patent 9,061,121 from the United States Patent Office was granted on June, 2015 and will expire August, 2031.

Additions

Conference presentations: (Number of abstracts, posters, and presentations given at international, national, or regional meetings between 7/1/2016 and 6/30/2017)

- July 2, 2016: On Human Growth and Form, Guest Lecture - Biotensegrity Symposium, Department of Anatomy, University of Dundee, Scotland
- July 3, 2016: Anatomy demonstrations, Biotensegrity model of Pelvic support anatomy, Department of Anatomy

- Poster May 16, 2017 AUA, Boston

Urodynamics/LUTD/Female Pelvic Medicine: Neurogenic Voiding Dysfunction

Poster MP85-19: "Side matters: Sacral neuromodulation lead placement on the less versatile side offers greater benefit in patients with asymmetry"

Usama Al-Qassab, Lindsey Hartsell, Joy Butterworth, John DeCaro, Niall Galloway

Other Presentations and Materials:

April 2017, Published Emory Anatomy APP - Male Pelvic Anatomy, now available in the App Store

Female Pelvic Anatomy APP - in development

Chapters/Textbooks:

Seeking Symmetry: Finding Patterns in Human Health

Niall Galloway with Sarah MacArthur Smith

Final manuscript and illustrations submitted September 2017 for publication in 2018, Handspring Publishers, Edinburgh, Scotland

Grant Leadership:

Coulter Foundation Partnership Grant awarded July 1st, 2017

PI: Niall Galloway

Title: Peri-Urethral Targeting and Delivery Device for the Treatment of Stress Urinary Incontinence in Women (attachment)

Bi-weekly meeting schedule, since June 14 and interval progress reports, and presentations to oversight committee

Leadership or Peer Review Role: (Had an active leadership role (such as serving on committees or governing boards) in national medical organizations or served as reviewer or editorial board member for a peer-reviewed journal between 7/1/2016 and 6/30/2017)

Editorial board European Urology - Reviewer

Georgia CTSA's Pilot Translational & Clinical Studies (PTCS) program - Reviewer

Teaching Formal Courses:

2017 Advances in Urology December 9, Debate "Mesh or No Mesh"

Invited Presentations for 2018

SESAUA 3/23/2018 Panelist Pediatric Sub-Plenary Session II - Ask the Experts: Neurogenic Bladder Care, Voiding Dysfunction and Transitional Care

Biotensegrity Interest Group and British Fascia Society - Pre-Conference Symposium, Keynote Speaker, May 11, 2018 Solihull, England

International Meetings attended

European Association of Urology, London, March 2017

International Continence Society, Florence, Italy September 2017 (Travel and meeting expenses included in Coulter award and funded by Coulter)

Coulter team presentation and half day meeting with prospective industry partner, Ontario Canada - October 18, 2017 (Travel expenses included in Coulter award and funded by Coulter)

Support of Emory Surgical Fellowship training programs

1. Reconstructive Urology Fellow Supervisor and Mentor of Candidate Lindsey Hartsell Emory University Department of Urology, One Year Fellowship in Reconstructive Urological Surgery. Graduated June 2017 and recruited successfully to Emory Faculty position. Current One year Fellow Sam David. Proposal to GURS granted in September 2017, Dr Jeff Carney has led this effort with support and assistance from all.
2. ACGME approved Uro-Gynecology Fellows (X3) Co-director of Urology, member of Curriculum committee, candidate selection and interview committees. Didactic lectures (Thursdays 7am) include pelvic anatomy, neuro-urology, physical examination skills and neuromodulation.

Updates for 2018

Invited Presentations for 2018

SESAUA March 23, 2018 Session Moderator and Panelist - Pediatric Sub-Plenary Session II

- Ask the Experts: Neurogenic Bladder Care, Voiding Dysfunction and Transitional Care

BIOTENSEGRITY INTEREST GROUP and British Fascia Society - Pre-Conference Symposium,

Keynote Speaker, May 11, 2018 Solihull, England

Title: On Human Growth and Form

INTERNATIONAL CONTINENCE SOCIETY August 27-30, 2018 Philadelphia PA

Moderator: General Session – Pot Pourri

Invited Speaker to International Meetings

September 29, 2018 World Education Day, Jinan, China

Session 6.2 Medical and Health Education

Title: Seeking Symmetry: Finding Patterns in Human Health

(<http://www.worldeducationday.org/scientificprogram.asp>)

How symmetry seeking can help to simplify the task of teaching Medicine.

December 6, 2018 Advancing Continence Care Forum, Gothenburg, Sweden

Title: Seeking Symmetry: Finding Patterns in Human Health

Encouraging Urologists to recognize clinical patterns of sacral neurogenic deficit and how to use physical examination findings in the feet to guide management of pelvic floor problems.

Upcoming International Meeting

May 13-15, 2019 Annual World Congress of NeuroTalk, Osaka, Japan. Session 6, Clinical Neuroscience

Session Moderator and Presenter

Title: Seeking Symmetry: Finding Patterns in Human Health <http://www.bitcongress.com/NeuroTalk2019/>

How the Neurologist can use pattern such as voicing and voiding. The larynx and urethra have shared embryological development, anatomy, physiology and similar patterns of disease and dysfunction.

Publishing

My book “Seeking Symmetry: Finding Patterns in Human Health” is now finished and available.

Published by Handspring of Edinburgh, Scotland Paperback: 192 pages

Handspring Publishing Ltd; 1 edition (September 30, 2018 US) Language: English

ISBN-10: 1912085119 and ISBN-13: 978-1912085118

Both Amazon and the Online Book Club site have posted independent complementary reviews

Emory Anatomy APP

In 2017, we published the first Emory Surgical Anatomy APP (available without charge in the APP store) on the subject of the Male Pelvis. We are committed to resume work on the companion project – The Female Pelvis and hope to publish in 2019.

Principal Investigator in ongoing Funded Research Projects

MyoSite Autologous muscle culture as bulking agent in the treatment of SUI in women.

Statement of Transactions Date: April 6, 2018 Office for Clinical Research, Grant 7395000001 (Date 17 Nov 2015 Award 0000037669 IRB IRB00089651 Project 00060098 Sponsor Cook Myosite Date Reference Transaction Amount Payments Received 4/6/2017 INV 7395000001-30355 Check 512363 \$13,150.00 7/12/2017 INV 7395000001-33052 Check 516332 \$975.00 11/22/2017 INV 7395000001-35649 Check 520616 \$1,560.00 \$15,685.00 Total Received: Date Reference Amount Unrealized Revenue 4/6/2018 INV 7395000001-39571 \$975.00 \$975.00 Total Unrealized Revenue.)

MyoSite Autologous muscle culture as a bulking agent in the treatment of SUI in Men. Study Closed July 2018

Co-Investigator with Dr Lindsey Hartsell and Dr Jeff Carney – Emory Pro-ACT Protocol# P130018/PAS001

Medical Device Development

Co-Investigator with Dr Jessica Hammond

In 2017, I secured a Coulter Partnership award to develop the hand assisted video endoscopic Peri-Urethral Targeting Device for the treatment of SUI in women. US Patent Ref: 08043 US: Letters of Patent #9,061,121 Further clinical use patents have been submitted and are under consideration by the US Patent Office.

With the help of the Coulter team, and after developing revised design specifications and building final prototypes in 2017, we have conducted successful bench testing and completed a simulated clinical use project, working with fresh human cadavers in the Department of Anatomy. Armed with an instructional video, professional drawings, new prototypes and simulation data, we approached potential industry sponsors to complete the process and pursue commercial production. Boston Scientific have been enthusiastic about our project and are now committed to partner with us to bring the product to market. A formal announcement by Emory University, Department of Technology Transfer is expected in the coming weeks. First in human use of our targeting and delivery device for urethral bulking to treat stress urinary incontinence in women is anticipated within 18 calendar months of signing.

ADDITIONS FOR 2019: In preparation for Chairman's Review June 21, 2019

Ongoing Support of Emory Urology Residency and Post Graduate Surgical Fellowship training programs

Reconstructive Urology Fellow: Supervisor and Mentor of One year Fellow Sam David 2018

GURS accredited in September 2017, Dr Jeff Carney has led this effort with support and assistance from all.

Graduating Reconstructive Fellow for 2019, Dr Madeline Cancian

ACGME accredited Uro-Gynecology Three year Fellowship (3 Fellows) Director Gina Northington MD of Uro-Gynecology leads this effort, my duties include Co-director of Urology, member of curriculum committee, candidate selection and interview committees. Monthly multidisciplinary meetings and regular didactic lectures (Thursdays 7am) include pelvic support anatomy, neuro-urology, clinical examination skills and surgical practice including neuromodulation.

Graduating UroGynecology PFMRS Fellow for 2019, Dr Alexcis Ford

**Publishing in 2019: Contribution to book on "Scars, Adhesions and the BioTensegrity Body"
Editors, Trewartha and Wheeler, Handspring Publishing**

2019 SESAUA Symmetry presentation: Detailed Examination of the Feet and Pelvic Floor Can Predict Severity of Urinary Incontinence.

Madeline Cancian, R. Grady Bruce, Rizk E. S. El-Galley, Niall T. M. Galloway

Emory/Boston Scientific Surgical Device Development project with Dr Hammett: We have made steady progress with refining the design features of a surgical instrument for the targeted delivery of periurethral bulking agents for the treatment of stress urinary incontinence in women. Prototypes have been evaluated in fresh porcine model and fresh tissue cadavers. The current iteration has been tested successfully in bench top models and awaits final revisions, we anticipate first in human use within the coming months.

October 5, 2019 Columbus GA WOCNSES Annual Meeting - Invited Speaker – "Seeking Symmetry: Finding Patterns in Human Health"

New Invitation to ICS Consensus Panel: On Diagnosis and Management of Vaginal Mesh Complications: The panel has been constituted this year to help to develop clinical guidelines to advance the recognition and optimal treatment strategies for complications arising from the use of vaginal mesh products. This international initiative launched in 2019, will include representatives from many different countries.

ICS 2019 Meeting September 2019: Accepted for Video Workshop on Native Tissue Surgical procedures for Incontinence and vaginal prolapse

1. Vesico-vaginal Fistula repair and Bilateral Colpopexy
2. Paravaginal Repair with the Aid of Vaginal Trans-illumination

International Invitation to speak at “BioTensegrity Europe 2020”: Invited Key Note Speaker and Panelist

Ongoing Clinical Research: Myosite study with Gina Northington and Lindsey Hartsell

Pro-ACT study with Dr Hartsell

New APP project with John Ogorek and Andy Matlock of Emory Department of Surgical Anatomy and Technique: 3-D Modeling of Pelvic Support Anatomy and Continence Mechanisms of the Female Pelvic Floor

EXHIBIT "B"

Niall Galloway
Materials Relied Upon

Document Date	Primary Author	Title	Publication
	Abbot, et al	Evaluation and Management of Complications From Synthetic Mesh After Pelvic Reconstructive Surgery: A Multi-Center Study	Presentation Number: Paper 29
2014-01-01	Abbott, et al	Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study	Am J Obstet Gynecol 2014;210:163.e1-8
2011-01-01	Abdel-Fattah, et al	Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: A Meta-Analysis of Effectiveness and Complications	European Urology 60 (2011) 468 - 480
2006-01-01	Abdel-Fattah, et al	How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure	BJU Int, 98(3), 594-598
2008-01-01	Abdel-Fattah, et al	Retrospective multicentre study of the new minimally invasive mesh repair devices for pelvic organ prolapse	BJOG 2008;115:22–30
	Abdel-fattah, et al	A RANDOMISED PROSPECTIVE SINGLE-BLINDED STUDY COMPARING "INSIDE-OUT" VERSUS "OUTSIDE-IN" TRANSOBTURATOR TAPES IN THE MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE (E-TOT STUDY); 3 YEARS FOLLOW-UP.	Poster 18
2010-01-01	Abdel-fattah, et al	Evaluation of transobturator tapes (E-TOT) study: randomised prospective single-blinded study comparing inside-out vs. outside-in transobturator tapes in management of urodynamic stress incontinence: Short term outcomes	European Journal of Obstetrics & Gynecology and Reproductive Biology 149 (2010) 106-111
2010-04-12	Abdel-fattah, et al	Randomised prospective single-blinded study comparing 'inside-out' versus 'outside-in' transobturator tapes in the management of urodynamic stress incontinence: 1-year outcomes from the E-TOT study	BJOG 2010;117:870—878
2010-05-18	Abdelwahab, et al	Tension-Free Vaginal Tape versus Secure Tension-Free Vaginal Tape in Treatment of Female Stress Urinary Incontinence	Current Urology, 4(2), 93-98
2011-01-01	Abed, et al	Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials; a systematic review	Int Urogynecol J (2011) 22:789–798
2011-01-01	Aboseif, et al	Treatment of moderate to severe female stress urinary incontinence with the adjustable continence therapy (ACT) device after failed surgical repair	World J Urol (2011) 29:249—253
2011-00-00	Aboushwareb, et al	Is Tissue Engineering and Biomaterials the Future for Lower Urinary Tract Dysfunction (LUTD)/Pelvic Organ Prolapse (POP)?	Neurourology and Urodynamics 30:775--782 (2011j

2009-01-01	Abramowitch, et al	Tissue mechanics, animal models, and pelvic organ prolapse: A review	European Journal of Obstetrics & Gynecology and Reproductive Biology 144S (2009) S146–S158
2011-01-01	Abrams, et al	Synthetic Vaginal Tapes for Stress Incontinence: Proposals for Improved Regulation of New Devices in Europe	European Urology 60:1207-1211
2006-12-01	ACOG	ACOG Committee Opinion Number 352: Innovative Practice: Ethical Guidelines	ACOG Committee Opinion No. 352
2007-02-01	ACOG	ACOG PRACTICE BULLETIN NUMBER 79: CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN-GYNECOLOGISTS	The American College of Obstetrics & Gynecology
2007-09-01	ACOG	ACOG PRACTICE BULLETIN NUMBER 85: CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN -GYNECOLOGISTS NUMBER 85	The American College of Obstetricians and Gynecologists
2005-06-01	Acog Committee on Practice Bulletins--Gynecology	ACOG Practice Bulletin Number 63: Clinical Management Guidelines for Obstetrician-Gynecologists	Obstet Gynecol
2017-04	Acog Committee on Practice Bulletins--Gynecology	ACOG Practice Bulletin Number 694: Management of Mesh and Graft Complications in Gynecologic Surgery	Obstet Gynecol
2008-10-01	Agarwala N	A Randomized Comparison of Two Synthetic Mid-Urethral Tension-Free Slings	UroToday International Journal / Vol 1 / Iss 4/
2007-01-01	Agarwala, et al	Laparoscopic sacral colpopexy with Gynemesh as graft material- Experience and results	Journal of Minimally Invasive Gynecology (2007) 14, 577–583
2014-01-01	Agnew, et al	Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence	Int Urogynecol J (2014) 25:235–239
2006-00-00	Agrawal, Avill	Mesh migration following repair of inguinal hernia: a case report and review of literature	Hernia (2006) 10: 79--82
2007-01-01	Albo, et al	Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence	N Engl J Med 2007;356:2143-55
2012-12-01	Albo, et al	Treatment Success of Retropubic and Transobturator Mid Urethral Slings at 24 Months	J Urol Vol. 188, 2281-2287
2009-00-00	Albrich, et al	Isolation of fibroblasts for coating of meshes for reconstructive surgery: differences between mesh types	Regenerative Medicine
2003-01-02	Almeida, et al	Use of Cadaveric Fascia Lata To Correct Grade IV Cystocele	International Braz J Urol Vol. 29 (1): 48-52

2011-01-01	Al-Omary, Atalla	Long term patient satisfaction after suburethral sling operation for stress incontinence	Int Urogynecol J (2011) 22 (Suppl 3):
2011-01-01	Altman, et al	Anterior Colporrhapy versus Transvaginal Mesh for Pelvic-Organ Prolapse	N Engl J Med 2011;364:1826-36
2007-02-01	Altman, et al	Perioperative Morbidity Using Transvaginal Mesh in Pelvic Organ Prolapse Repair	Obstet Gynecol 2007;109:303–8
	Altman, et al	INTRA- AND PERIOPERATIVE MORBIDITY FOLLOWING PELVIC ORGAN PROLAPSE REPAIR USING A TRANSVAGINAL SUTURE CAPTURING MESH DEVICE COMPARED TO TROCAR GUIDED TRANSVAGINAL MESH AND TRADITIONAL COLPORRAPHY	Abstract
2007-01-01	Altuna,et al	Lower urinary tract injuries associated with the out-in transobturator tape - is cystoscopy required An Argentinean multicenter experience	Int Urogynecol J (2007) 18 (Suppl 1):
2009-01-01	Amaro, et al	Clinical and Quality-of-Life Outcomes after Autologous Fascial Sling and Tension-Free Vaginal Tape: A Prospective Randomized Trial	International Braz J Urol Vol. 35 (1):60-67
1997-01-01	Amid PK	Classification of biomaterials and their related complications in abdominal wall hernia surgery	Hernia (1997) 1:15-21
2010-01-01	Ammembal, Radley	Complications of polypropylene mesh in prolapse surgery	OBSTETRICS, GYNAECOLOGY AND REPRODUCTIVE MEDICINE 20:12, 359-364
1998-01-01	An, Friedman	Concise review of mechanisms of bacterial adhesion to biomaterial surfaces	J Biomed Mater Res (Appl Biomater) 43: 338—348
2008-01-01	Anderson, et al	Foreign Body Reaction to Biomaterials	SEMIN. IMMUNOL. 20(2): 86-100
1985-01-01	Anderson, HA	Utilization of Adipose Tissue Biopsy in Characterizing Human Halogenated Hydrocarbon Exposure	Environmental Health Perspectives
2007-01-01	Andonian, et al	Prospective Clinical Trial Comparing Obtape and DUPS to TVT: One-Year Safety and Efficacy Results	European Urology 52 (2007) 245-252
2005-01-13	Andonian, et al	Randomized Clinical Trial Comparing Suprapubic Arch Sling (SPARC) and Tension-free Vaginal Tape (TVT): One-Year Results	European Urology 47 (2005) 537—541
2015-00-00	Anger, Elber	Risks of transvaginal mesh may be associated with an increased risk of urinary retention and reintervention	BMJ
2007-01-01	Anger, et al	Complications of Sling Surgery Among Female Medicare Beneficiaries	Obstet Gynecol 2007;109:707–14
2010-01-01	Angioli, et al	Tension-Free Vaginal Tape Versus Transobturator Suburethral Tape: Five-Year Follow-up Results of a Prospective, Randomised Trial	European Urology 58 (2010) 671-677

2009-01-01	Aniuliene R	Tension-free vaginal tape versus tension-free vaginal tape obturator (inside-outside) in the surgical treatment of female stress urinary incontinence	Medicina (Kaunas) 2009; 45(8)
1986-03-22	Anon	Epistemology of Surgery	The Lancet
2009-01-01	Araco, et al	The influence of BMI, smoking, and age on vaginal erosions after synthetic mesh repair of pelvic organ prolapses. A multicenter study	Acta Obstetrica et Gynecologica. 2009; 88: 772—780
2008-01-24	Araco, F. et al	TVT-O vs TVT: a randomized trial in patients with different degrees of urinary stress incontinence	Int Urogynecol J (2008) 19:917–926
2012-01-01	Arrabal-Polo, et al	Complications from the Placement of a Tension-Free Suburethral Sling Using the Transobturator and Retropubic Methods for Treatment of Female Urinary Incontinence	Urologia Internationalis
2003-01-01	Arunkalaivanan, Barrington	Randomized trial of porcine dermal sling (Pelvicol implant) vs. Tension-free Vaginal Tape (TVT) in the Surgical treatment of stress incontinence: a questionnaire-based study	Int Urogynecol J (2003) 14: 17—23
	Arunkalaivanan, et al	SINGLE-INCISION MIDURETHRAL TAPE (OPHIRA) VS TRANSOBTURATOR TAPE (OBTRYX): PROSPECTIVE COMPARATIVE STUDY- 2 YEAR FOLLOWUP	Abstract 245
2009-01-01	Arunkalaivanan, et al	Efficacy and safety of transobturator tape (Obtryx) in women with stress urinary incontinence and intrinsic sphincter deficiency	Presentation 778
2008-00-00	Atassi, et al	Haemorrhage and nerve damage as complications of TVT-O procedure: case report and literature review	Arch Gynecol Obstet, 277(2), 161-164
2013-01-01	Athanasidou, et al	Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: Why do tapes fail?	Int Urogynecol J
2009-01-01	Athansiou, et al	MIXED URODYNAMIC INCONTINENCE: TVT or TVT-O?	Int Urogynecol J (2009) 20 (Suppl 2):S73–S239
2011-11-01	AUA	AUA Position Statement on the Use of Vaginal Mesh For the Repair of Pelvic Organ Prolapse	American Urological Association
2012-04-01	AUA	ADULT URODYNAMICS: AUA/SUFU GUIDELINE	American Urological Association Education and Research, Inc.
2009-01-01	AUA	Guideline for the Surgical Management of Female Stress Urinary Incontinence 2009 Update	
2011-11-01	AUA	AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence	
2013-01-01	AUGS	Guidelines for Privileging and Credentialing Physicians for Sacrocolpopexy for Pelvic Organ Prolapse	Female Pelvic Medicine & Reconstructive Surgery, 19, 2

2011-07-01	AUGS	AUGS Response FDA Safety Communications	American Urogynecologic Society
	AUGS	Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders	American Urogynecologic Society
2011-09-09	AUGS	AUGS statement September 8-9, 2011	AUGS
2012-01-01	AUGS	Guidelines for Providing Privileges and Credentials to Physicians for Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse	Female Pelvic Medicine & Reconstructive Surgery Volume 18, Number 4
2014-01-01	AUGS and ACOG	Committee Opinion: Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment	Female Pelvic Medicine & Reconstructive Surgery 20; 5: 248 - 251
	AUGS, SUFU	Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	
2014-01-03	AUGS-SUFU	Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	
2009-01-01	Aungst, et al	Do novo stress incontinence and pelvic muscle symptoms after transvaginal mesh repair	Am J Obstet Gynecol 2009;201:73.e1-7
2006-01-01	Babalola, et al	Vaginal erosion, sinus formation, and ischiorectal abscess following transobturator tape: ObTape implantation	Int Urogynecol J (2006) 17: 418—421
2004-00-00	Bader, et al	Cystocele repair by vaginal approach with a tension-free transversal polypropylene mesh	Gynécologie Obstétrique & Fertilité 32 (2004) 280--284
2005-10-01	Baessler, et al	Severe Mesh Complications Following Intravaginal Slingplasty	Obstet Gynecol 2005;106:713--6)
2006-01-01	Baessler, Maher	Mesh augmentation during pelvic-floor reconstructive surgery: risks and benefits	Curr Opin Obstet Gynecol 18:560--566
2006-01-01	Bahadur, Sastry	Principles of Polymer Science, 2nd Edition	
2009-01-01	Bako, Dhar	Review of synthetic mesh-related complications in pelvic floor reconstructive surgery	Int Urogynecol J (2009) 20:103-111
	Balachandran, Duckett	LONG-TERM 6 YEAR PATIENT SATISFACTION AND QUALITY OF LIFE OUTCOMES AFTER AN ADVANTAGE SLINGS FOR STRESS URINARY INCONTINENCE	Abstract
2008-08-01	Balakrishnan, et al	Prospective evaluation of the safety and efficacy of the Apogee system for treatment of vault prolapse	Journal of Obstetrics and Gynaecology; 28(6): 618--620
	Balmforth, Cardozo	PROSPECTIVE MULTICENTRE OBSERVATIONAL TRIAL OF COMPOSITE POLYGLACTIN/POLYPROPYLENE MESH (VYPRO* MESH) FOR RECONSTRUCTION OF RECURRENT ANTERIOR VAGINAL WALL PROLAPSE	Poster
2011-01-01	Bandarian, et al	Comparison of transobturator tape (TOT) vs Burch method in treatment of stress urinary incontinence	Journal of Obstetrics and Gynaecology, August 2011;31:518-520

2016-00-00	Bang, Belal	Autologous pubovaginal slings: back to the future or a lost art?	Research and Reports in Urology
2006-01-01	Banks, et al	Abscess formation following trans-obturator tape procedures	Int Urogynecol J (2006) 17 (Suppl.. 2):
2005-12-01	Barber M	Contemporary views on female pelvic anatomy	Cleveland Clinic Journal of Medicine VOLUME 72 SUPPLEMENT 4
2013-01-01	Barber M	Surgical Techniques for Removing Problematic Mesh	CLINICAL OBSTETRICS AND GYNECOLOGY Volume 56, Number 2, 289–302
2006-01-01	Barber, et al	Perioperative complications and adverse events of the MONARC transobturator tape, compared with the tension-free vaginal tape	American Journal of Obstetrics and Gynecology (2006) 195, 1820–5
2012-01-01	Barber, et al	Single-Incision Mini-Sling Compared With Tension-Free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial	Obstet Gynecol 2012;119:328–37)
2008-00-00	Barber, et al	Risk factors associated with failure 1 year after retropubic or transobturator midurethral slings	Am J Obstet Gynecol 199, 666 e1-7
2008-03-00	Barber, et al	Transobturator Tape Compared With Tension-Free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial	Obstet Cynecol 2008;111:611--21
2000-01-01	Barber, et al	Bilateral uterosacral ligament vaginal vault suspension with site-specific endopelvic fascia defect repair for treatment of pelvic organ prolapse	Am J Obstet Gynecol 2000;183:1402-11
2009-01-01	Barber, et al	Defining Success After Surgery for Pelvic Organ Prolapse	Obstet Gynecol 2009;114:600–9
1997-01-01	Barksdale, et al	Intraligamentous Nerves as a Potential Source of Pain After Sacrospinous Ligament Fixation of the Vaginal Apex	Int Urogynecol J 8:121-125
2015-02-28	Barone, et al	The impact of boundary conditions of surface curvature of polypropylene mesh in response to uniaxial loading	Journal of Biomechanics
2016-00-00	Barone, et al	Textile properties of synthetic prolapse mesh in response to uniaxial loading	Am J Obstet Gynecol
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EXHIBIT “C”**Litigation List of Dr. Niall Galloway, updated – August 18, 2019**

Case List - includes all Mesh Litigation, including all Final Reports and deposition testimony

Lisa Fontes	Joann Serrano	Debbie Jilovek	Mary Weiler
Caroline McCabe	Darlene Dennis	Stephanie Najor	Sylvia Hogan
Alease Allen	Bonnie Pattison	Cynthia Anderson	Janet Holt
Cheryl Hellbusch	Sharon Morris	Heatherly case	Kathy Pierce
Alina Fitzgerald	Mary Shelton	Donna Bihlmeyer	Karen Swanson
Margaret Carroll	Marilyn Muir	Myra Heuer	Dina Bennett
Tina Morrow	Charlene Taylor	Carey Cole	Melissa Clayton
Beth Harter	Angela Morrison	Margaret Stubblefield	Wendy Hagans
Lois Durham	Jackie Frye	Mary Holzerland	Victoria Rock
Barbara Massicot	Karen Daniel	Corriveau case	Jeannie Smart
Shirley Denton	Cynthia Raines	Juliet Chirino	Jenny Santiago
Donna Wheeler	Doris Howe	Ruth Franklin	Ingrid Beregszazy
Maria Odonez	Twana Rose-Carter	Rebecca Smiley	Carol Byers
Donna J Conti	Stephany Dierking	Eugenia Smith	Bonnie Evans
Armentha Price	Amy Harrison-Hood	Barbara Bagwell	Debra Eagan
Rosie Larkins	Terressa Williams	Stephanie Lenderman	Sherri Bolinger
Anne Richard	Jeannie Smart	Rebie Dixon	Rowena Crowe
Katrina McPherran	Martha Stevenson	Maria Robinson	

Dr. Galloway Testimony at Trial in Mesh Litigation Cases

Diane Albright	Martha Carlson	Rhonda Orozco
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EXHIBIT "D"

Niall T M Galloway – Fee Schedule

Medical Record Review or Deposition Review - \$600/ hour

Expert Report required in the Carbon case - \$6,00.00

NTMG